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              UNITED STATES DISTRICT COURT
            FOR THE NORTHERN DISTRICT OF OHIO
2
                    EASTERN DIVISION
3
    IN RE: NATIONAL
                                     MDL No. 2804
    PRESCRIPTION OPIATE
    LITIGATION
                                    Case No.
                                     1:17-MD-2804
5
    THIS DOCUMENT RELATES TO
                                    Hon. Dan A.
    ALL CASES
                                )
                                    Polster
7
8
9
                   Sunday, May 5, 2019
10
11
       HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
12
                 CONFIDENTIALITY REVIEW
13
14
15
16
           Videotaped Deposition of MEREDITH B.
     ROSENTHAL, Ph.D., VOLUME 2, held at Robins
17
     Kaplan LLP, 800 Boylston Street, Suite 2500,
     Boston, Massachusetts, commencing at
     8:04 a.m., on the above date, before
18
     Michael E. Miller, Fellow of the Academy of
     Professional Reporters, Registered Diplomate
19
     Reporter, Certified Realtime Reporter and
20
     Notary Public.
21
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           Golkow Litigation Technologies
18
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3		May 5, 2019	
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1	PROCEEDINGS
2	(May 5, 2019 at 8:04 a.m.)
3	THE VIDEOGRAPHER: We're now on
4	record. My name is Vince Rosica. I'm
5	a videographer for Golkow Litigation
6	Services. Today's date is May 5th,
7	2019, and the time is 8:04 a.m.
8	This video deposition is being
9	held in Boston, Massachusetts in the
10	matter of National Prescription Opiate
11	Litigation, MDL No. 2804 for the
12	Northern District of Ohio, Eastern
13	Division Court.
14	The deponent is Meredith
15	Rosenthal.
16	Counsel will be noted on the
17	stenographic report.
18	The court reporter is Mike
19	Miller and will now swear in the
20	witness.
21	(Witness sworn.)
22	MR. SOBOL: Before you begin, I
23	think the professor had one quick
24	update.
25	THE WITNESS: Yes. Remember

```
yesterday you were asking me about if
1
2.
            I had testified in other litigation
3
            related to opioids, and I knew that I
4
            had been retained in a case, and I
5
            could not remember whether I had
6
            actually testified. So I looked that
7
            up, and indeed, sometime around five
8
            years ago, not recently enough to
            appear in the case captions that I
9
10
            list at the back of my CV, I testified
11
            in a matter related to Actiq, the
12
            Cephalon drug.
13
                   MR. ROTH: You anticipated my
14
            very first question.
15
                   THE WITNESS: Excellent.
16
              MEREDITH B. ROSENTHAL, Ph.D.,
17
           having been previously duly sworn,
18
                 testified as follows:
19
     BY MR. ROTH:
                   What was the nature of your
20
            Ο.
21
     expert opinion in that case?
22
                   I did a damages analysis for
     class certification proceedings.
23
                   And was it limited to a single
24
25
     manufacturer?
```

- A. Yes, it was a single drug,
- single manufacturer. I can't recall the
- details. I didn't go all the way back to the
- 4 complaint, but it was an off-label marketing
- 5 case.
- 6 Q. And do you recall whether you
- y used a regression analysis in that case?
- 8 A. I did not.
- 9 Q. Okay. May have more questions,
- but that's good for now.
- Professor Rosenthal, you
- mentioned a couple of times yesterday that
- you excluded injectables from your analysis?
- A. Yes, that's right.
- Q. Why did you do that?
- 16 A. That was in consultation with
- counsel. So I understood they were not to be
- considered in the matter, and I understand
- 19 from clinical experts that the uses of the
- injectables are somewhat different than the
- orals.
- Q. Do you know anything about
- whether the marketing for injectables differs
- from the marketing for the oral opioids?
- 25 A. I do not.

- 1 Q. Your model does not attribute
- any causality to manufacturers based on
- alleged deficiencies in the suspicious order
- 4 monitoring regime?
- 5 A. My assignment was to examine
- the impact of the allegations with regard to
- marketing, and so I have not specifically
- 8 looked at the impact of any
- 9 monitoring-related allegations.
- 10 Q. And that would be true also for
- the distributors and the pharmacies; because
- your allegations relate to marketing, you
- have not included them in any of your
- 14 analyses in your reports?
- MR. SOBOL: Objection.
- A. Again, my assignment was to
- examine the impact of the alleged unlawful
- marketing. I have not considered other
- conduct in my analysis.
- BY MR. ROTH:
- Q. We spoke yesterday about
- 22 endogeneity, and I think I marked as
- Exhibit 14 an article you wrote for the
- 24 Kaiser Family Foundation, if you could pull
- that up, please.

- 1 A. Let me see if Mike organized my
- documents. Yes. Go ahead.
- ³ Q. You testified yesterday that
- 4 endogeneity did not need to be controlled for
- in your model because it's an aggregate
- 6 model.
- 7 A. Yes.
- Q. Are you aware of any economic
- 9 literature that does control for endogeneity
- in an aggregate model measuring the impact of
- 11 promotion on sales?
- 12 A. An industrywide aggregate model
- like mine, I'm not aware of one.
- Q. And is there a difference in
- your mind between industrywide versus
- 16 classwide?
- 17 A. Yes, there is. Again, if the
- notion is that whatever causes the
- endogeneity has to be either some kind of
- simultaneous decision-making around price and
- quantity, for example, or a feedback loop,
- and at the level of the industry, that's
- simply not plausible, that the industry is
- coordinating its marketing in that way.
- Q. Your model in this case though

```
is not actually an industrywide model, is it?
1
2.
                   Again, industrywide for the
            Α.
3
     opioid industry?
                   Well, except you take out all
4
5
     of the non-defendants from your model?
6
            Α.
                   Well, that's not true. The
7
     model is all of the -- all of the opioids.
     The but-for scenario takes -- leaves the
8
9
     non-defendants as they were, but the model
10
     concludes all of them.
11
            Ο.
                   Right. So in the but-for
12
     scenario where you take out the
13
     non-defendants, what did you do to compare
14
     their promotional activities to the
     defendants' promotional activities?
15
16
                   MR. SOBOL: Objection.
17
            Α.
                   Well, such a comparison is not
18
     part of the overall analysis. Again, we've
19
     talked about the Table C, which presents the
20
     marketing by defendants and non-defendants,
     so the data are in there.
21
22
                   The model itself includes
23
     marketing for all opioids, and the but-for
24
     scenario simply disaggregates and identifies
     as a part of that process the marketing of
25
```

- non-defendants, but it does so only to
- 2 generate different predictions of what sales
- would have been, so there -- I did not make a
- 4 statistical comparison between non-defendant
- 5 and defendant promotion.
- 6 BY MR. ROTH:
- 7 Q. When you removed the
- 8 non-defendants, what did you do to confirm
- that that did not take out, for example, the
- non-rivalrous marketing and leave you with a
- set of just the rivalrous marketing?
- MR. SOBOL: Objection.
- A. What I'm examining in my
- 14 aggregate model is the net effect, rivalrous
- market expanding of promotion, and so the
- model calculates that average market
- expansion effect and essentially all of the
- rivalrous marketing, it nets out by
- definition because to the extent that we're
- talking about rivalrous marketing as defined
- 21 as moving market shares from one drug to the
- other, which is basically the definition of
- rivalrous marketing, all the pluses have to
- net out with the minuses.
- 25 And so that -- that does not

- appear in the output of my model because it's
- 2 not relevant to my assignment. So by taking
- out all of the -- actually, technically, it's
- 4 sort of a double negative. I actually leave
- in all of the non-defendant promotion in the
- 6 but-for scenario because it would have
- 7 happened regardless of whether the
- 8 allegations are true or not.
- 9 By leaving that in, if it has
- 10 rivalrous components to it, if it has market
- expanding components to it, whatever that is
- will show up in my predictions.
- 13 BY MR. ROTH:
- Q. Yeah. What I'm trying to
- understand is I think we agree that when you
- look at an individual manufacturer there
- could be endogeneity issues in the form of
- price or in the form of detailing physicians
- who are predisposed to prescribe their
- product?
- A. If we were looking at an
- individual manufacturer, we could have some
- of those endogeneity concerns, but I do not
- look at an individual manufacturer.
- Q. I understand that.

```
1
                   Even if we look at a group of
2.
     manufacturers, we would still have
3
     endogeneity concerns to a degree?
4
                   MR. SOBOL: Objection. Excuse
5
               Asked and answered.
                   It's my opinion that in this --
6
           Α.
7
     when we're looking at the level of the entire
8
     opioid industry, that the conceptual basis
     for such endogeneity concerns is really not
10
     there, and even -- even if at the second
11
     stage of my analysis I parse out some subset
12
     of defendant, of manufacturers, sorry,
13
     non-defendants, in particular, that in and of
14
     itself doesn't raise a new endogeneity
15
     concern. The model is estimated on the
16
     marketwide effects.
17
     BY MR. ROTH:
18
                   I'm trying to figure out where
19
     the line is though. So like how many
20
     manufacturers need to be included for all of
21
     the endogeneity and rivalrous marketing
22
     issues to just net out and show market
23
     expansion as opposed to the effects of just
24
     the subset you're looking at?
25
                   MR. SOBOL: Objection to the
```

```
1
            form.
2.
                   You can answer.
3
            Α.
                   The rivalrous marketing will
4
     always net out. Again, it's just
5
     mathematically true that by definition,
6
     marketing that only moves market share, it
7
     has to net out. So that's just an identity.
8
                   That will always be true when
9
     we look at any subgroup of products that
10
     we -- that the rivalrous piece will net out.
11
     It just has to.
12
     BY MR. ROTH:
13
                   What about endogeneity?
            Ο.
14
            Α.
                   The endogeneity issue in my
15
     opinion is where we have the entire opioid
16
     class in the analysis. It does not make
17
     sense to think about this month-to-month
18
     reverse causality for marketing as a whole
19
     for the industry, relative to sales as a
20
     whole for the industry. It's not how
21
     individual companies set their marketing
22
     budgets.
23
                   It just doesn't make economic
24
     sense to me, so for the analysis at hand,
25
     looking at the entire opioid industry, I do
```

- 1 not believe that there's a conceptual basis
- for the same endogeneity concerns that we
- might have with an individual drug or an
- 4 individual company.
- 5 Q. Your analysis compares your
- 6 industrywide but-for scenario against a
- 7 scenario with just the defendant
- 8 manufacturers, correct?
- 9 MR. SOBOL: Objection.
- 10 A. So my analysis ultimately
- compares the predicted -- the actual
- predicted sales, so that's leaving everything
- the same with a world in which we pull out
- some subset of the marketing.
- 15 BY MR. ROTH:
- Q. So what I'm trying to
- understand is I understand your position on
- the big but-for scenario with the whole
- industry, but why is endogeneity not a
- 20 concern for the pulled-out set of
- 21 manufacturers?
- MR. SOBOL: Objection.
- A. There's no estimation that's
- going on there, so endogeneity is a concern
- when we're estimating parameters using a

- 1 regression model. It is not -- the second
- stage of my analysis is simply employing
- those parameters to predict a different
- scenario, and so endogeneity, it's -- it's
- 5 not a relevant construct for that prediction
- 6 piece.
- 7 BY MR. ROTH:
- 8 Q. If you look at Exhibit 14, this
- 9 was the article you prepared for the Kaiser
- Family Foundation in 2003, and if you look at
- page 2, the last paragraph on the page, you
- say: In this paper, we examine the effects
- of two types of promotional spending for
- brands in five therapeutic classes of drugs,
- using monthly aggregate data from August 1996
- through December 1999.
- Do you see that?
- 18 A. I do.
- 19 Q. So you actually looked at five
- different classes of drugs. Do you recall
- what drugs they were?
- A. Antidepressants, nasal sprays,
- nonsedating antihistamines, PPI's, which are
- proton pump inhibitors, and number 5, let me
- just look at -- there are some tables that

- are probably the easiest place. I'm blanking
- on the fifth one. Cholesterol,
- 3 anticholesterol drugs.
- Q. Turn to page 14, please.
- 5 A. Okay.
- Q. And on page 14 you say: We
- 7 take account of the possibility that spending
- 8 on direct-to-consumer advertising and
- 9 physician promotion and product sales are
- jointly determined by estimating instrumental
- variables, IV, models where all three
- variables are assumed to be endogenous.
- Do you see that?
- 14 A. Yes.
- Q. And I think you said yesterday
- this article only solved for endogeneity at
- the product level?
- A. I believe so, yes.
- Q. Okay. And if you look at the
- bottom of page 9, in the last paragraph it
- says: At the top level of the tree, which
- represents the therapeutic class of drugs, we
- estimate the impact of DTCA spending and
- detailing in the context of a Cobb-Douglas
- demand specification, double logarithmic. In

- the analysis of competition at the individual
- 2 product level within each class we specify
- and estimate three alternative models: 1, an
- 4 AIDS-type specification; 2, a logit model
- with log of quantity share divided by, one
- 6 minus quantity share, on the left-hand side,
- and prices and promotional spending on the
- 8 right-hand side; and 3, a Cobb-Douglas model
- 9 in log levels.
- Do you see that?
- 11 A. Yes, I do.
- Q. And then on page 15, under
- Econometric Results, it says: We begin by
- presenting results in Table 3 for the top of
- the tree structure in Figure 2, the class
- level quantity equations.
- Do you see that?
- 18 A. I do.
- 19 Q. And then if you look at
- Table 3, which is on page 25, the top two
- lines say: Class DTC and Class Detail, and
- they have an asterisk that says Endogenous,
- 23 IV Estimated.
- Do you see that?
- A. Yes, I do. Actually, I can

- 1 keep reading, but I think essentially the
- class level estimates are the sum of the
- individual product level estimates. So
- 4 again, the instrumentation was at a product
- 5 level.
- 6 Q. And then applied to the class
- 7 level through aggregation?
- 8 A. That's right.
- 9 Q. Okay. And if you had
- disaggregated individual drugs or
- 11 manufacturers in this case, you could have
- applied an instrumental variables method to
- each and aggregated them similarly here?
- MR. SOBOL: This case, the
- opioids case, not this?
- MR. ROTH: Correct, so let me
- 17 reask it.
- MR. SOBOL: Yeah.
- 19 BY MR. ROTH:
- Q. If you had used disaggregated
- individual drugs or manufacturers in the
- opioids case we're talking about now, you
- could have applied an instrumental variables
- model to each individual drug and then
- aggregated them as you did in this article?

- A. Unlike the research question in this paper, my assignment asks me to compute
- 3 the impact of the alleged misconduct at the
- 4 level of the class, the industry, opioid
- industry as a whole. And so it was not
- 6 appropriate for me to look at individual drug
- ⁷ level analyses.
- 8 I maintain that at that class
- 9 level, industry level, these endogeneity
- questions do not pertain.
- 11 Q. Did you test that hypothesis by
- looking at an individual defendant or two to
- see how the issues there compare to how your
- model handles endogeneity?
- A. Since my assignment was an
- aggregate assignment, I have conducted my
- analysis at the aggregate level. I have not
- conducted my analysis at the level of an
- individual defendant.
- Q. And, in fact, to confirm,
- you've not reviewed any individual
- defendant's marketing materials for any drug
- 23 at issue in this case?
- MR. SOBOL: Objection, asked
- and answered.

- 1 A. I'm not sure what you mean by
- that exactly. I reviewed the documents that
- you see I relied on in my report. I would
- 4 consider those to be marketing materials.
- 5 BY MR. ROTH:
- 6 Q. You've not reviewed any
- 7 manufacturer's marketing plan for any drug at
- 8 issue in this case?
- 9 MR. SOBOL: Objection.
- 10 A. Again, I'm not sure that that's
- entirely correct. I do cite to what I would
- consider to be marketing plans.
- 13 BY MR. ROTH:
- Q. Okay. Aside from the documents
- reflected in Attachment B or cited in your
- report, you've not reviewed any marketing
- materials for any drugs at issue in this
- case?
- A. Aside from materials cited in
- my report, I've certainly not relied on any
- of those marketing materials.
- Q. And aside from the depositions
- reflected in Attachment B, you've not
- reviewed any depositions from any
- manufacturer's sales representatives?

1 Α. Aside from the depositions that 2. I cite in my report, I'm not relying on any 3 other deposition testimony, no. 4 You've not reviewed any 5 testimony or other direct evidence from 6 doctors about how they were affected by a 7 given manufacturer's promotion? 8 MR. SOBOL: Objection. 9 Α. As I note in my report, as an 10 economist, asked to examine the impact of the 11 alleged marketing misconduct, interviewing 12 physicians would not be a scientifically 13 appropriate methodology to ascertain impact. 14 We know that self-report is unreliable, particularly when it comes to 15 16 behavior that may be socially unacceptable. 17 BY MR. ROTH: 18 So if doctors from Summit or 0. 19 Cuyahoga County testified at trial that they 20 were detailed but it didn't affect them, as 21 an economist, you would dismiss that 22 testimony? 23 MR. SOBOL: Objection. 24 As an economist, I would rely Α.

on the evidence about what people do and not

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25

- what people say. It's been demonstrated in
- the literature, literature that I cite in my
- report, that again, that self-report is not a
- 4 reliable basis for ascertaining impact, so I
- would not rely on physician self-report.
- 6 BY MR. ROTH:
- 7 Q. If defendants presented
- 8 testimony from 15 doctors at trial who all
- 9 said their prescribing practices were
- unaffected by opioids promotion, would your
- position be different?
- 12 A. I do not believe that numeracy
- overcomes bias. There's no scientific basis
- for such a conclusion, so no, I do not
- believe that physician self-report is
- reliable, even if there are 15 physicians.
- Q. So in your view as an
- economist, the testimony of any number of
- doctors regarding how they viewed the effect
- of defendants' promotion has no relevance?
- A. I would not draw any conclusion
- from such testimony for the purposes that my
- report has been set forth.
- Q. You did not review any
- manufacturer's disaggregated marketing data

```
1
     for the purpose of your analysis?
 2.
                   MR. SOBOL: Objection, form.
 3
            Α.
                   Again, in my report I cite
 4
     certain documents that have data in them
 5
     related to marketing. I do not use those
 6
     data in my calculations.
 7
     BY MR. ROTH:
 8
            Q.
                   And I think you said yesterday,
 9
     you made a very specific request to look for
10
     such data.
                 Do you remember that?
11
            Α.
                   I did, yes.
12
                   And why did you ask for that?
            O.
13
            Α.
                   When I started my work, I
14
     wanted to know about what all the possible
15
     data sources that would be available were.
16
                   And if you had a more robust
            Ο.
17
     source of disaggregated marketing data across
18
     defendants, would you have used that to model
19
     promotion instead of the IQVIA data that you
20
     used?
21
                   MR. SOBOL: Objection.
22
                   I can't say for sure, but I
            Α.
23
     wanted to find all the data that I could
24
     from -- from discovery.
```

///

25

BY MR. ROTH: 1 2. You did not review any Ο. 3 manufacturer's detailing call notes? 4 I did not review any detailing 5 call notes, no. 6 And I think you said this Ο. 7 yesterday, but just to confirm, you did not 8 comprehensively review all of any given 9 manufacturer's marketing budgets for a 10 specific drug in this case? 11 MR. SOBOL: Objection, asked 12 and answered. 13 I did not systematically review Α. 14 those marketing budgets, no. 15 BY MR. ROTH: 16 And so when you calculate the 17 percentages in Table 3 of your report, as we 18 discussed, that's just a comparison of 19 removing each defendant's promotional 20 contacts in the data from the aggregate 21 model? 22 MR. SOBOL: Objection, asked 23 and answered. 24 Table 3 presents alternative Α. 25 simulations of but-for scenarios in effect,

- in which individual defendants are -- their
- 2 marketing efforts are deemed to be not
- subject to recovery of any kind, and so that
- 4 those marketing efforts are left in the
- 5 but-for scenario.
- 6 So it is a -- it's a product of
- ⁷ the regression -- my direct regression model.
- 8 BY MR. ROTH:
- 9 Q. I want to work with you on a
- hypothetical. So let's assume that no opioid
- marketing occurred beginning in 1993.
- 12 A. No opiate -- opioid marketing
- 13 at all?
- Q. Correct, no promotion, no IQVIA
- 15 contacts.
- A. Okay.
- Q. So in your model --
- MR. SOBOL: I'm sorry, just so
- it's clear, do you mean that or the
- 20 broader --
- MR. ROTH: Well, let's start
- with -- that's fair.
- MR. SOBOL: You know what I
- 24 mean?
- MR. ROTH: That's fair.

BY MR. ROTH: 1 2. So let's start with no Ο. 3 promotion at all, no marketing, no detailing, 4 no articles, nothing, a world without 5 promotion, okay? 6 Α. Okay. 7 MR. SOBOL: Sounds wonderful. 8 BY MR. ROTH: 9 All right. So if promotion 10 hadn't occurred since 1993, the only thing 11 your model would use would be price and the 12 constant terms. 13 MR. SOBOL: Objection. 14 But you can answer. 15 BY MR. ROTH: 16 Correct? Ο. 17 Α. You're sort of suggesting that 18 the underlying data would be totally 19 different, but yes, the -- if the stock of 20 promotion is always zero, then it wouldn't 21 enter into the estimation, so it would be 22 price and the constant term, yes. 23 Ο. What does your model say the level of sales would be if the stock of 24

promotion is always set to zero?

25

- 1 A. Well, again, you're
- constructing a hypothetical that's outside of
- the world in which I'm actually putting this
- 4 model together, but it would depend on the
- 5 level of sales.
- 6 Essentially, as you can see in
- my indirect model, price would cause a small
- 8 decline in sales over the time period.
- 9 Q. So would it show any sales?
- 10 A. Well, your hypothetical is --
- you didn't tell me what the baseline level of
- sales was.
- Q. Okay. So assume a small
- baseline level of sales. It would start
- there and decline over time? Is that what
- you're saying?
- 17 A. Yes.
- Q. Okay. So -- and the reason for
- that is because all of the sales in your
- model are explained by marketing as
- counterbalanced by price?
- A. Well, again, you have to take
- into account the specifics of the
- specification I used. So the sales are
- explained by marketing in combination with

- the depreciation rate in combination with the
- specific functional form I use.
- Your hypothetical is not one
- 4 that makes any sense to me as a health
- economist, and it's generally good practice
- in applied economic analysis to not
- 7 extrapolate too far outside of the world
- you're analyzing. So we don't want to
- 9 forecast 50 years out from this model.
- Likewise, to apply it to a
- world in which there's no marketing when that
- is so different from the world that we're in,
- is -- it's a stretch that doesn't make a lot
- of sense to me as a hypothetical.
- Q. But in order to test whether
- your model allows for anything but marketing
- to cause sales, does it not make sense to set
- marketing at zero?
- 19 A. It does not make sense to me to
- set marketing at zero. That's not something
- I would do in a model like this.
- Q. All right. If we do set
- marketing to zero, however, it shows that no
- other factors are driving an increase in
- sales in your model?

- A. In the model, if -- if

 promotion were at zero, Model C might look

 different. In fact, promotion is the

 dominant factor driving sales, so what you're

 saking is a hypothetical that essentially
 - assumes away what we know the fundamental
 - 7 sales driver is in this industry, and so it's
 - 8 a nonsensical hypothetical to me.
 - 9 Q. And when you say you know the
- fundamental sales driver for opioids is
- 11 marketing, how do you know that?
- 12 A. Look at Dr. Perri's report.
- 13 Look at any of the articles that we've talked
- about. Promotion is critically important in
- the pharmaceutical industry.
- 16 Q. That's an assumption you're
- making based on Dr. Perri, not something that
- you've studied specifically in the opioid
- industry before, correct?
- MR. SOBOL: Objection.
- Objection, asked and answered.
- A. That's -- it's based on
- economic theory. It's based on economic and
- marketing analysis. It's not an assumption
- that I'm just taking from Dr. Perri.

```
1
     BY MR. ROTH:
2.
                   So in your view, a model that
            Ο.
3
     allows for nothing but promotion to predict
4
     positive sales is reasonable because you
5
     believe promotion is what drives marketing
6
     for opioids?
7
                   MR. SOBOL: Objection.
8
                   MR. ROTH: Sorry, that was a
9
            bad question. Let me rephrase it.
10
     BY MR. ROTH:
11
                   In your view, a model that
            0.
12
     allows for nothing but promotion to predict
13
     positive sales is reasonable because you
14
     believe promotion is what drives sales for
15
     opioids?
16
                   MR. SOBOL: Objection.
17
            Α.
                   I think there are many issues I
18
     would have with that statement. So, first of
19
     all, my model is looking at the extent to
20
     which promotion is driving increases in
21
     sales.
22
                   As we talked about at length
23
     yesterday, there may be things that affect
24
     whether a particular patient or a particular
25
     physician uses a specific medicine.
                                            What I'm
```

- trying to explain is growth over time, so
- that's not the same as what might explain
- 3 levels.
- 4 Second, I would say that the
- 5 model demonstrates that promotion causes
- sales. It is not an inherent assumption.
- 7 The basic structure of my model is the same
- 8 as the models in the published papers that we
- 9 looked at that use aggregate time series data
- because in time series, we're looking at the
- 11 factors that drive changes over time, and
- prices and promotion are those factors.
- 13 BY MR. ROTH:
- 14 Q. In your view, your model proves
- the hypothesis that promotion of opioids
- drives increased sales of opioids?
- 17 A. Yes, that is the conclusion I
- reach in my report.
- Q. And before you put your
- regression model together, you believed that
- 21 promotion of opioids drove sales of opioids?
- A. As a health economist and as
- someone who's done work in this area before,
- my priors were that promotion is an important
- factor in causing sales increases, yes.

```
And, in fact, nothing aside
 1
            Ο.
 2.
     from promotion in your model would allow for
 3
     an increase in the sales of opioids?
 4
                   MR. SOBOL: Objection.
 5
            Α.
                   In setting up the model, before
     doing the analysis, while I expected prices
 6
 7
     to have the relationship with sales that they
 8
     did, I did not know whether the prices, as we
     discussed yesterday, would be rising or
 9
10
     falling.
11
                   So as a matter of specifying
12
     the model, the effect of prices could have
13
     been either to accelerate or decelerate
14
     growth.
15
     BY MR. ROTH:
16
                   That was a good answer, but I
17
     don't think it directly responded to my
18
     question.
19
                   In your model --
20
                   MR. SOBOL: That's a
21
            contradiction.
22
     BY MR. ROTH:
23
            0.
                   In your model, there is nothing
24
     aside from increased promotion that causes an
25
```

increase in the sale of opioids?

1 MR. SOBOL: Objection, asked 2. and answered. 3 Α. Again, in the model as 4 specified, prices could have had either a 5 positive or negative effect, not because the 6 coefficient could have been positive or 7 negative, but because the trend could have 8 been positive or negative. 9 In practice, when I estimated 10 the model, the underlying data suggested that 11 prices were, in fact, increasing, and thus 12 decreasing sales, and so promotion is the 13 single variable in Model B that is causing 14 increases in sales. 15 In Model C, as we talked about 16 yesterday, one of the dummy variables appears 17 positive in a way that is counterintuitive; 18 nonetheless, it accounts for some of that 19 sales growth. 20 BY MR. ROTH: 21 You included no other variables 22 in your direct regression model beyond price 23 and promotion; is that right? 24 In Model B, I include price, 25 promotion, the constant, and I estimate the

- depreciation rate.
- In Model C, I include those
- 3 five event dummies.
- Q. What did you do to measure the
- 5 impact of non-defendant promotion on market
- 6 expansion?
- 7 MR. SOBOL: Objection, asked
- and answered.
- 9 A. My model is an aggregate model
- and the estimation includes defendants and
- non-defendants, and so the coefficient
- estimated on promotion in the model pertains
- to the impact of both defendants and
- 14 non-defendants.
- 15 BY MR. ROTH:
- Q. Your but-for world in your
- model excludes defendant promotion?
- 18 A. The but-for scenario excludes
- defendant promotion, yes.
- Q. What is the result if the
- but-for world excludes all promotion and
- 22 keeps all else equal?
- A. I have not been asked to look
- 24 at a but-for scenario. As we were talking
- before about the idea of zero promotion,

- that's not a scenario I've looked at.
- 2 Q. You spoke a minute ago about
- Model C. I want to come back to that for a
- 4 minute.
- If you turn to Table 1.
- 6 A. 47.
- 7 Q. Thank you.
- A. Mine is getting well leafed.
- 9 Q. And actually, that's not the
- one I want. I'm sorry. I went the wrong
- 11 way. I actually want Attachment D, the table
- that shows your coefficients for Model C.
- 13 A. Okay.
- Q. So I think it's D.8.
- 15 A. No.
- 16 Q. No, D.8. Table D.8.
- 17 A. Oh, Table D.8, sorry.
- 18 Q. Yeah. You numbered the tables
- the same way as the pages. It makes it
- confusing.
- A. Very confusing, okay.
- Q. So in Table D.8, the stock of
- promotion with the trend for the period
- starting in August 10 is negative; is that
- 25 right?

1 Α. That's right. 2. And you maintain the negative Ο. 3 depreciation rate, which means sort of 4 growing stock of promotion even in that 5 period? 6 Α. Right. 7 And we spoke about that a 8 little bit yesterday, but can you just explain for me why it is that the 9 10 effectiveness of promotion as a whole is 11 declining but the stock of promotion 12 continues to grow in the third period of your 13 model? 14 MR. SOBOL: Asked and answered. 15 You can answer. 16 Α. The depreciation rate, I Yes. 17 estimate a single depreciation rate over the 18 entire time period, and it's my belief that 19 the negative depreciation rate reflects the 20 addictive nature of opioids. 21 That does not change in the 22 latter part of the period, so despite the 23 fact that the marginal productivity of promotion is declining over that period, the 24 25 idea that the stock of promotion continues to

- grow is not conceptually inconsistent.
- 2 BY MR. ROTH:
- Q. We agree that all detailing is
- 4 not equally effective?
- MR. SOBOL: Objection.
- A. I -- here I am trying to
- 7 estimate -- I am estimating the average
- 8 effect of detailing. There may be some
- yariation in that effect, but I'm interested
- in the aggregate impact.
- And so the fact that my
- 12 analysis averages across some -- some
- variation is not mathematically a problem.
- 14 It will still lead me to the right answer in
- terms of the aggregate impact.
- 16 BY MR. ROTH:
- 17 Q. I assume you agree based on the
- way you've constructed Model B that the
- effectiveness of detailing changes over time?
- A. That is what Model B captures.
- Q. Right. Detailing that may have
- been effective earlier in time may become
- less effective over time as new information
- 24 comes to light?
- A. Well, I think the premise

1 you're suggesting there is, again, it ignores 2. the addictive nature of the product, so once 3 a patient is using opioids and has increasing 4 needs for higher doses; whether or not the 5 specific messages are still in the mind of 6 their physician, they are nonetheless 7 addicted to the product or tolerant of the 8 product and requiring higher and higher doses 9 which will show up in my data as higher and 10 higher MMEs. 11 So I can't quite agree with the 12 premise and its relevance to the analysis. 13 Based on your last answer, I 14 assume you'd agree that when a patient 15 receives higher doses of opioids, that may be 16 a sign of tolerance as opposed to addiction? 17 Α. Yes, higher doses may be 18 tolerance and not necessarily addiction. 19 Again, I'm not a clinical expert, so I want 20 to be careful not to go too far with that. 21 In fact, a patient who is being 22 successfully treated with opioids for chronic 23 pain may become tolerant and need a higher 24 dose to achieve the same pain deterrent

effect?

25

```
1
            Α.
                   I think we're getting a little
2.
     too far out of my expertise and into clinical
3
     questions.
4
            Ο.
                   Do you believe that promotion
5
     has a greater impact on the very first
6
     prescription a physician writes for a therapy
7
     like opioids or for subsequent prescriptions
8
     the physician may write for the same drug?
9
                   MR. SOBOL: Objection.
10
                   I'm not sure it makes
            Α.
11
     conceptual sense to distinguish that.
12
     think that there is a -- there is an inherent
13
     connection that happens when someone starts
14
     on a medicine. They have a higher
15
     probability of being on that medicine next
16
     month than someone who didn't start, right,
17
     so that -- that would be a natural underlying
18
     connection between the two things.
19
                   It may be that promotion also
20
     has a reminder effect, and so that would be
21
     an increment in addition to the fact of that
22
     patients once on a drug may be likely to stay
23
     on a druq.
24
                   I have not tried to distinguish
25
     those factors.
```

1 BY MR. ROTH: 2. Is that an issue that you have Ο. 3 studied or seen economic literature on, 4 whether promotion is more effective at 5 getting doctors to initiate a therapy versus 6 maintain a therapy they've already used in 7 the past? 8 Again, for the purposes of my Α. 9 analysis, I had no need or wish to 10 distinguish between those things. I can't 11 point to a paper right now, but I believe 12 that maybe someone has done that. 13 I assume you're aware there are 14 different classes of opioids, correct? 15 There are different molecules, Α. 16 like oxycodone and hydrocodone, is that what 17 you're referring to when you say classes? 18 Well, there are different Ο. molecules, that's one thing. 19 20 Α. Yes. There are different 21 22 formulations, right? 23 Α. Yes. There are different methods of 24 Ο.

25

administration?

1 Α. Yes. 2. There's a patch, right? Ο. 3 Α. Yes. 4 Q. There's that sublingual spray? Α. 5 Yes. And then there's pills and 6 Ο. injectables, for example? 7 8 Α. Yes. 9 MR. SOBOL: Film. 10 BY MR. ROTH: 11 Ο. Film? 12 Yes, I'm aware that there are Α. 13 different formulations. 14 Ο. And there's also immediate-release opioids and 15 16 extended-release opioids, correct? 17 Α. Yes, that's correct. 18 And for the purpose of your 19 models, apart from the injectables, all of 20 those various forms of opioids are included? 21 Yes, that's correct. Α. 22 Did the manufacturers' Ο. 23 marketing budgets that you reviewed show 24 increased marketing spending over time? 25 Α. As I sit here, I don't recall.

- Q. Would you agree that if the
 depreciation rate augments the stock of
 detailing over time, it would be irrational
 to keep spending money on promotion?
 - MR. SOBOL: Objection.
- A. No, I don't think that that
- 7 would be a conclusion that I would agree
- 8 with.
- 9 BY MR. ROTH:
- Q. And why not?
- 11 A. The more effective your
- marketing is, the more you want to spend on
- 13 it.
- MR. SOBOL: An answer I
- understood.
- 16 BY MR. ROTH:
- Q. We spoke briefly about your
- errata yesterday. Can you just tell me how
- did that errata come about?
- 20 A. That came about from review
- 21 partly, my very careful review as I was
- preparing for this deposition, and the staff
- doing the same.
- 24 Q. Got it.
- And then why did it come in the

- form of a memo from Mr. McCluer to you and
- 2 Mr. Sobol?
- A. I'm not sure I can answer that
- 4 question.
- 5 Q. But it sounds like the errors
- 6 were identified some by you and some by the
- 7 staff?
- A. Yes, that's correct.
- 9 Q. Do you know who caught the
- 10 Table 3 error?
- 11 A. That was me.
- 12 O. I feel bad for the staff on
- that one. And what about the --
- 14 A. I'm not the yelling type.
- Q. And what about the statistical
- significance error, was that you or the
- 17 staff?
- 18 A. That was the staff.
- 19 Q. Let's turn to your indirect
- model.
- A. Okay.
- Q. So you talk about your indirect
- model beginning at paragraph 78 of your
- report.
- And I guess just taking a step

- back before we get into specifics: Do you
- have a preference for your direct over your
- 3 indirect model in this case?
- 4 A. I believe they have strengths.
- 5 Each of them has strengths, so in my
- opinions, I have not favored one over the
- other.
- Q. In general when you perform
- 9 regression analysis, do you have any
- preference for a direct approach versus an
- indirect approach?
- 12 A. No preference. I think these
- kinds of models are really context specific.
- Q. And if you look at page 53,
- paragraph 78, you start by saying: As noted
- earlier, the direct method of estimation is
- limited in part by the extent to which we can
- measure and include in the models all of the
- tactics allegedly employed by defendants,
- including manipulation of various
- 21 professional societies and accrediting
- 22 bodies.
- Did I read that correctly?
- A. Yes, you did.
- Q. And that's based on the

- allegations that you reviewed?
- A. That's correct.
- Q. Would you agree that if a
- 4 defendant did not engage in promotion other
- 5 than the detailing measured by the IPS data,
- the direct model would be a more appropriate
- 7 measure of that particular defendant's impact
- 8 on the aggregate MMEs?
- 9 A. My assignment was to calculate
- aggregate impact, so I have not considered
- 11 how to calculate impact for a single
- defendant.
- 13 As we talked about yesterday, I
- think there are some complicated questions
- about how to deal with the spillover effect,
- so I have not undertaken to do that.
- Q. As we've discussed fairly
- exhaustively, your direct Model B explains
- over 99% of the variation in MME sales based
- on the detailing data in IQVIA.
- A. Yes, it does.
- Q. Does that not suggest that the
- effect of all of these other types of
- promotion is negligible at best?
- A. It may well be the case that

- the amount of variation that is picked up by
- a broader measure of promotion would not be
- 3 so much more. The indirect model is
- 4 conceptually quite different, however.
- 5 Q. So if you compare Table 5,
- 6 which is on page 61 -- let's take a step
- back, lay some foundation.
- 8 A. Sure.
- 9 Q. So Table 5 on page 61 is the
- output of your indirect model, correct?
- 11 A. It is.
- Q. Okay. We talked yesterday
- about Table 2, which is the output of your
- direct model and appears on page --
- 15 A. Should I bend the corner so we
- can go back and forth?
- Q. Yes, good idea.
- So I want to compare the direct
- output in Table 5 on page 61 -- sorry, strike
- that.
- I want to compare the indirect
- model output in Table 5 on page 61 with the
- direct model output in Table 2 on page 51.
- A. Okay.
- MR. SOBOL: Do we have a graph

```
of this somewhere?
1
2.
                  THE WITNESS: Not in my report.
3
                  MR. ROTH: Just for you.
4
           don't think we've seen that. I would
5
           love to see it.
6
     BY MR. ROTH:
7
                  So looking at the two tables
8
     next to each other, I guess just first taking
     the bottom line, in Table 2, the direct Model
9
10
     B estimates that of MMEs are
11
     attributable to defendants' detailing.
12
                  Do you see that?
13
           Α.
                  Yes.
14
                  And in Table 5, the indirect
           0.
     method suggests that of MME shipments are
15
16
     attributable to defendants' detailing; is
17
     that right?
18
           Α.
                  That's correct.
19
           Ο.
                  So that's a delta -- well,
20
     that's a bad question because that's not how
21
     math works.
22
                  MR. SOBOL: Right.
23
     BY MR. ROTH:
24
                  It's higher -- well, the
25
     numbers are what they are, but it's
```

-- it's actually higher, I think, 1 2. if I'm doing the math right. 3 Α. It is percentage points or 4 higher than the direct estimate. 5 You said it better than I Ο. 6 could. 7 How is that possible given that 8 you had a 99% R-squared in the direct model that your indirect model could estimate twice 10 as much impact by defendants' promotion? 11 Α. As I mentioned, they are 12 conceptually very different kinds of 13 analyses, so whether or not detailing 14 explains the vast majority of the variation 15 in sales, it does not account for -- it 16 accounts for a smaller percentage of total 17 sales, so the magnitude of effect is not the 18 same thing as the amount of variation 19 explained, right? 20 And the indirect model takes 21 the position that there are these long run 22 factors that may -- that we can see are 23 relevant to demand in -- across areas, and if we extend those forward, looking at the 24 25 growth in MMEs only as a result of those

- factors, that's another version of what the
- world would have been like.
- It assumes, again, that the
- 4 drivers of the massive growth we saw were
- only related to defendant promotion, and so
- 6 it allows defendant promotion to affect sales
- in a broader way than the direct model does.
- 8 Q. In the direct model, I believe
- you went through 2018; is that right?
- 10 A. Yes. There were differences in
- data availability, so yes.
- Q. Right. So that was what I was
- going to ask you.
- Direct goes through 2018,
- indirect only goes through 2016?
- A. Yes. And as I'm sure we'll get
- to also, because the ARCOS data start in
- 18 1997, I do, I backcast for '95 and '96, but
- really I'm starting in 1997.
- Q. Got it. So direct, you go '95
- to 2018; indirect, you go from '97 to 2016.
- A. That's correct.
- Q. Okay. And that's just because
- of just data limitations?
- A. That's correct.

- Q. If you had the other years, you would use them in the indirect model?
- A. That's correct.
- 4 Q. If you look at paragraph 82 of
- your report, you describe your indirect model
- 6 as a form of residual analysis.
- 7 Do you see that?
- 8 A. Yes.
- 9 Q. And can you explain what a
- residual analysis is?
- 11 A. Well, a residual is the
- leftover part, and so a residual analysis is
- an analysis that draws inferences not from
- something included, but something excluded.
- Q. Sort of like in accounting,
- when you depreciate something, what's left
- after you've depreciated it is the residual?
- 18 A. Is it? Yeah, perhaps.
- Q. Except if the depreciation
- somehow appreciates, but we won't go there
- 21 again.
- What is the baseline of your
- 23 indirect model?
- A. The baseline for the indirect
- model as I just mentioned is the 1997 level

- of MMEs.
- Q. And you chose that because that
- was the earliest year available in ARCOS?
- 4 A. Yes, that's correct.
- 5 Q. How did you construct the
- 6 explanatory variables you used in the
- 7 indirect model?
- 8 A. The explanatory variables come
- 9 from a variety of sources that I think we
- reviewed at a very high level yesterday.
- They're county level -- we haven't exactly
- talked about. So this is a county level
- cross-sectional analysis and we bring in data
- from a variety of government economic sources
- and other sources to capture county-level
- 16 information.
- Q. And we spoke about this a
- 18 little yesterday with respect to Professor
- 19 Cutler.
- 20 A. Yes.
- Q. But the same question for you:
- Why did you decide to use national data and
- do a national model for direct regression,
- but then do your indirect regression analysis
- based on county-level data?

```
1
                   MR. SOBOL: Objection, asked
2.
           and answered.
3
           Α.
                   Sure. The time series analysis
4
     that I did is appropriately done at the
5
     national level. We're trying to calculate
6
     national aggregate impact and the factors
7
     that drive sales over time make sense to do
8
     in -- at a national level there. We don't
9
     have promotional data at a county level, so
10
     it would not be possible to do a direct model
11
     at this level.
12
                   On the other hand, and this is
13
     why the indirect model complements the direct
14
     model, we can look cross-sectionally at
     variation in these socioeconomic and
15
16
     demographic variables because there's a fair
17
     amount of cross-sectional variation, and get
18
     reasonably precise estimates of the effect of
19
     those factors on MMEs.
20
                   And so the cross-sectional
21
     model works at the county level, and then
22
     rather than having to estimate the effects of
23
     those variables over time, we can trend them
     forward based on the cross-sectional
24
25
     analysis.
```

1 BY MR. ROTH: 2. If you look at paragraph 79, Ο. 3 which is on page 53, you say: The indirect 4 model begins with a regression analysis of 5 the relationship between opioid sales and the 6 demographic, economic and healthcare 7 characteristics of an area ideally during the 8 period prior to the misconduct. 9 Do you see that? 10 Α. Yes, I do. 11 So what do you mean when you Ο. 12 say ideally it would be from the period prior 13 to the misconduct? 14 Well, to the extent the Α. 15 misconduct is affecting the relationships 16 between the right-hand side variables, those 17 are the demographic, socioeconomic and 18 healthcare variables that we include, 19 estimation during this period could -- could 20 affect the results. 21 And again, the level of MMEs in 22 1997, if the allegations are true, are 23 already affected by the misconduct, but I believe this makes my analysis conservative 24 25

by starting two years into the damage

- period -- or not the damage period, but the
- period of alleged misconduct.
- Q. So you're taking data from the
- 4 period of alleged misconduct in 1997 because
- your assumption is the period of alleged
- 6 misconduct will be proven back to 1995?
- 7 A. That's correct.
- Q. And you say this makes it
- 9 conservative because the factors may have
- already been influenced and thus there would
- be a higher likelihood to see prescriptions
- 12 from the demographic factors which have some
- effect of the misconduct already?
- A. Potentially.
- Q. Okay. And what would be your
- basis to think that the demographic, economic
- and healthcare characteristics in Summit or
- Cuyahoga Counties were already seeing the
- effects of opioids in 1997?
- A. Wait, so just to be clear,
- 21 actually, the -- what you just said doesn't
- quite make sense, so let me just -- I
- probably should have provided a much longer
- answer to the last question.
- So what the two things that

1 starting the analysis in 1997 do. One is I 2. start already with a level of MMEs that if 3 the allegations are true, they're inflated. 4 And, two, what I was trying to 5 say is it's not that the socioeconomic status 6 of the counties is affected, although that 7 can certainly happen in the long run, but 8 instead that the relationship between 9 socioeconomic status and MMEs may have 10 already been affected by the promotion. 11 So, you know, if, for example, 12 the marketing is differentially affecting 13 certain groups, then that could show up in 14 the cross-sectional analysis, and so that's 15 what I meant. 16 And the reason you say it's 17 conservative is because directionally you 18 would think that the marketing would cause 19 those factors to predict more MMEs than they 20 would absent the marketing having already 21 occurred? 22 And again, the first Α. Yes. 23 part, the fact that the levels directionally, 24 again, under the assumption that the alleged 25 misconduct had been occurring for two years,

- the levels would certainly be inflated
- 2 relative to a but-for scenario in which there
- 3 was no misconduct.
- Q. Do you agree that for an
- 5 indirect regression you should include any
- 6 variable that might impact opioid sales?
- 7 A. For the indirect regression, I
- 8 am including all the variables that should be
- 9 cross-sectionally associated with that, so
- they -- just to be clear, that these are
- variables that can be measured at a county
- level, so not individual patient level, but
- at a county level will vary across counties
- and will predict use.
- Q. And if there are variables that
- are cross-sectionally related to sales that
- are omitted, that could cause issues with
- overestimating the amount of sales impacted
- by promotion?
- A. In any regression model, an
- 21 applied economist will have to consider the
- possibility of omitted variables. It is also
- in tension with the idea that if you throw in
- hundreds of variables, you get nonsense soup
- out of it, and so there's always going to be

- some tension there, but certainly one
- 2 considers important omitted variables.
- Q. Yeah, I mean, if I understand
- 4 it, the point of an indirect regression is to
- 5 essentially solve for a variable by including
- 6 everything but that variable that explains or
- 7 could explain the outcome?
- A. Yes. I just want to be clear
- 9 that the word "everything" makes it seem like
- you could actually estimate a regression with
- 11 hundreds of variables. There are degrees of
- 12 freedom. There can be problems from trying
- to put everything in.
- So in principle, you're right.
- We're trying to make sure that we include the
- important factors, and I believe I have done
- so here.
- Q. Okay. So I want to talk a
- little bit about the mechanics first.
- So you look at opioid shipments
- by county, correct?
- A. That's correct.
- Q. And why did you use shipments
- in your indirect model as opposed to
- 25 prescriptions?

1 These are words that describe Α. 2. the same thing in effect. So these are the 3 ARCOS data. They use the terminology 4 shipments. They don't track prescriptions. 5 They track controlled substances that move 6 from one set of hands to another. And so 7 these are using their nomenclature. 8 At the end of the day, I --9 these are MMEs, just like my MMEs in the 10 direct model. They correspond. And, in 11 fact, if you graph the two sets of data, 12 they're very close. 13 Can the IQVIA NPA data be 14 disaggregated to a county level? 15 It cannot. Actually, I'm not a Α. 16 hundred percent sure as I sit here. Again, 17 as we talked about yesterday, it's the 18 detailing data that definitely can't be 19 disaggregated. I can't remember whether the 20 NPA can be disaggregated too. 21 So as you sit here, you're 22 not --23 MR. SOBOL: You mean on its own 24 as opposed to using other tools? 25 MR. ROTH: No, I just mean

- generally.
- 2 BY MR. ROTH:
- Q. My question, just asking it
- 4 more broadly, is -- and it sounds like you
- don't know the answer, so let me strike that
- 6 and start with a clean question.
- 7 You don't know whether you
- 8 could have used the same IQVIA data for MMEs
- 9 used in your direct model in your indirect
- model at a county level?
- 11 A. I don't. I think the NPA is
- just a national-level dataset. I did compare
- 13 MMEs in total in the ARCOS data to the IQVIA
- data, and I found them to be almost
- 15 identical.
- I note one place where the
- 17 ARCOS data are not detailed enough to allow
- me to omit certain Schedule III codeines and
- 19 hydrocodones, I think. Yeah.
- Q. And that was going to be my
- next question.
- A. Sure.
- Q. So if you had used IQVIA data,
- you could have taken out the Schedule IIIs,
- but because you used ARCOS data, you had to

```
1
     leave certain Schedule IIIs in your analysis?
2.
                   That's correct. They're not --
3
     you can't identify them because the data
4
     aren't granular enough.
5
                   And I note in my report that
6
     that affects about 2?%. Just to be clear, I
7
     realized it's not an error, but it's not a
8
     hundred percent clear that that 2?% is really
     of those classes, of those molecules that
10
     have both Schedule II and Schedule III drugs,
11
     it's less than 1% of the total.
12
                   So again, when I compared the
13
     ARCOS MMEs and the IQVIA MMEs, they look
14
     almost identical.
15
                   (Interruption by the reporter.)
16
                   MR. ROTH: I think we need a
17
            quick break.
18
                   THE VIDEOGRAPHER: The time is
19
            9:04 a.m. We're off the record.
20
                   (Recess taken, 9:04 a.m. to
21
            9:16 a.m.)
22
                   THE VIDEOGRAPHER: The time is
23
            9:16 a.m. We're back on the record.
     BY MR. ROTH:
24
25
            Ο.
                   Just to go back to something we
```

- were talking about before the break, so your
- testimony is that picking '97 is conservative
- because the unlawful conduct based on your
- 4 assumptions started in '95, correct?
- 5 A. Yes.
- Q. You are aware that many of the
- 7 drugs at issue in this case were not on the
- 8 market in 1997?
- 9 A. I'm aware that certainly some
- of the drugs enter later, yes.
- 11 Q. So for manufacturers who did
- not have any drug on the market in '97 or
- even '98 or '99 or until later, you actually
- did choose a pre-misconduct period for those
- manufacturers?
- A. Well, again, I have been asked
- to characterize the aggregate impact of
- marketing on sales here, so I haven't -- and
- 19 I'm certainly not a lawyer, but I haven't
- given a thought to allocating liability
- 21 across defendants in any way. I would
- acknowledge that some defendants entered
- later than that with some drugs.
- Q. Right. And because you looked
- at an aggregate, if a single manufacturer had

- a product on the market, the remaining
- 2 manufacturers would all be subject to
- whatever the aggregate model shows as the
- 4 impact from that one product even though it
- 5 wasn't theirs?
- 6 MR. SOBOL: Objection.
- 7 A. Well, I think that you
- 8 misunderstood the cross-sectional analysis.
- 9 So again, the cross-sectional analysis is
- really capturing the effect of things like
- the age distribution and employment and the
- 12 like. So that's not a question of something
- to which liability is being attached.
- So it's really just trying to
- get a precise measure of those effects, and
- yes, that's the basis for projecting forward,
- but the projections forward, they don't
- assign any liability to those early
- relationships.
- BY MR. ROTH:
- Q. And just so we're perfectly
- clear, none of the models or the work you've
- done to date allows you to allocate liability
- to an individual defendant in this case,
- 25 correct?

```
1
                   MR. SOBOL: Objection.
2.
                   I don't know the answer to that
            Α.
3
     question because I don't know how liability
4
     would be allocated.
                           The models calculate
5
     aggregate impact, and as I've shown in
6
     Table 3, we can change that aggregate.
7
                   It is possible -- again, I
8
     haven't been asked to do this, but it is
     possible to use a similar approach to
10
     construct one kind of liability allocation,
11
     which would be to look at the levels of
12
     detailing across defendants and use that in
13
     Table 3 in a different way.
14
     BY MR. ROTH:
15
            Q.
                   None of the work or models
16
     you've done in this case allow you to
17
     allocate liability to a specific defendant
18
     based on only that defendant's alleged
19
     promotion?
20
                   MR. SOBOL: Objection, asked
21
            and answered.
22
                   Well, again, I'm not a lawyer,
            Α.
23
     but it seems to me that one method of
     allocating liability is in proportion to
24
25
     one's detailing efforts, and I have an
```

- aggregate impact that can be allocated in
- proportion to detailing using a similar
- approach to the way Table 3 assesses
- 4 aggregate impact for different combinations
- of defendants.
- 6 BY MR. ROTH:
- 7 Q. So I understand that your
- 8 Table 3 allows you to allocate to defendants
- their share of the promotional contacts in
- the data, correct?
- MR. SOBOL: Objection, asked
- and answered.
- 13 A. It is not based just on their
- share of the promotional contacts, but it's
- based on the difference in aggregate
- prescribing that would occur with and without
- their marketing happening.
- So it's not -- as we talked
- about yesterday, it's not strictly -- it goes
- through the model.
- BY MR. ROTH:
- Q. Okay. Your assignment was to
- develop an aggregate model of the impact of
- detailing on MMEs, correct?
- MR. SOBOL: Objection.

- A. Just to be crystal clear, my
 assignment was to estimate aggregate impact
- 3 using the best available methods.
- 4 BY MR. ROTH:
- 5 Q. Right. And you've said
- 6 numerous times throughout the last two days
- 7 that your assignment was not to determine
- 8 liability, correct?
- 9 A. Yes. I am -- I am not going
- to -- my opinions relate to the effect of
- 11 marketing, and how that relates to liability
- and recovery is not part of my assignment.
- Q. Okay. So unless the court
- allows the plaintiffs to prove liability
- based on each individual defendant's share of
- aggregate marketing, you have no mechanism to
- allocate liability on an individual defendant
- 18 basis?
- MR. SOBOL: Objection, asked
- and answered.
- A. I think you're asking me for a
- legal opinion. I don't know. It seems that
- the court could -- could allow plaintiffs to
- 24 allocate liability in a number of different
- ways. I don't know how that would work.

```
1
     BY MR. ROTH:
2.
                   I understand that. I'm not
           Ο.
3
     asking you for a legal opinion. I just want
4
     to understand what you're going to do at
5
     trial, okay? Okay?
6
                   MR. SOBOL: The buzzword is --
7
           when you're using the word "liability"
8
            in the question, that's the buzzword
9
            that's sending her down that road. So
10
            if you -- I'm coaching you now.
11
                   MR. ROTH: Well, I understand
12
           that, but I'm also trying to -- I know
13
           you guys want ultimate flexibility on
14
           your side but you shouldn't have it on
15
            this point, so I want to make sure the
16
            record is clear, okay?
17
     BY MR. ROTH:
18
                   Professor Rosenthal, your
19
     regression models that you have done to date
20
     do not allow you to allocate causation to
21
     individual defendants in any way other than
22
     as a ratio of those defendants' detailing
23
     contacts against the market aggregate
24
     detailing contacts?
25
                   MR. SOBOL: Objection to form,
```

1 asked and answered. 2. But you may answer. 3 Α. You have used the terminology 4 as a ratio, and that is not what happens in 5 Table 3. 6 So again, I don't know what the 7 court will want, but what I can do with my 8 aggregate model is I can use the econometric 9 results and create different but-for 10 scenarios, one set of which would be to focus 11 on individual defendants isolated from 12 others. 13 That's similar to what I've 14 done in Table 3, but that's not allocating 15 based on a ratio. It's rerunning the but-for 16 scenario, the predictions using a defendant's 17 detailing, and that detailing is not just a 18 single number. It's a time series. 19 BY MR. ROTH: 20 Q. Let me try this again. 21 Your regression models that you 22 have done do not allow you to allocate 23 causation to individual defendants in any way 24 other than separating out those defendants' 25 detailing contacts from the market aggregate

```
1
     detailing contacts?
2.
                   MR. SOBOL: Objection to form,
3
            asked and answered.
4
                   My analysis allows me to
5
     predict but-for prescriptions based on any
6
     level of detailing, including the assumption
7
     that only a single defendant's detailing was
8
     unlawful, and there may be other ways of
9
     using the aggregate model to estimate
10
     liability, except that I'm not a liability
11
               There may be other ways that I just
     expert.
12
     don't know of.
13
                   I can identify MMEs.
                                          I can
14
     identify detailing for each defendant. That
15
     information may be used in other ways that I
16
     haven't thought of because I don't know what
17
     the court will need.
18
     BY MR. ROTH:
19
                   How do your models allow you to
20
     predict but-for detailing assuming only a
21
     single defendant's detailing was unlawful
22
     without running afoul of the endogeneity
23
     issues that we've discussed?
24
                   MR. SOBOL: Objection.
25
                   You can answer.
```

1 Α. Because again, the endogeneity 2. issues are in the estimation of the 3 parameters. The but-for scenarios take the 4 estimates that are created at the aggregate 5 level, and they feed into it an alternative 6 set of detailing information. So they're 7 post-estimation. 8 Endogeneity is pre-estimation, 9 and all I'm doing is changing the simulation 10 of the but-for scenario. 11 BY MR. ROTH: 12 Let's go back to the indirect Q. 13 model for a bit. 14 Based on your assertion that 15 opioid pharmaceutical efforts are national in 16 scope and that marketing messages are 17 developed as a whole, would you expect a 18 single detail in one county to have the same 19 effect as a single detail in another county? 20 MR. SOBOL: Objection. 21 You can answer. 22 Α. I don't know what the 23 variability and the effect of detailing is 24 I expect that there would be some variation in the effectiveness of detailing 25

- 1 from situation to situation.
- 2 And my model and my assumptions
- in the indirect model, since I don't model
- 4 promotion directly, is that what I'm aiming
- to calculate is the average effect, and
- therefore, calculate the aggregate impact
- ⁷ from that average.
- 8 BY MR. ROTH:
- 9 Q. Is it possible that shipments
- to a county could understate or overstate
- consumption of opioids in that county?
- 12 A. Yes, it is possible that
- shipments to a county -- so once we get to
- the county level, there are -- there are
- issues related to diversion.
- Q. And I think Professor Gruber
- describes that as a transshipment problem in
- his report?
- 19 A. I think he does. There's a
- fancy name for the Florida transshipments, I
- can't remember what it was called, but yes.
- Q. Did you consider using
- geographic designations that account for
- 24 commuting patterns?
- A. No, I did not. The

- 1 county-level data I think are the most
- ² appropriate level of analysis. Any
- geographic unit will have some people moving
- in and out, but the county level, I think is
- 5 an appropriate level of analysis.
- The economic and
- 7 sociodemographic -- demographic and
- 8 socioeconomic variables are measured at the
- 9 county level, and we think about these sort
- of economic issues as being approximately
- captured at the county level.
- Q. Did you consider core-based
- statistical areas instead of counties?
- 14 A. I did not.
- Q. For the same reason that you
- 16 just gave?
- 17 A. Yes. There are -- the ARCOS
- data are at the county level, and again, most
- economic data are tracked at the county
- level. There are some data that are focused
- on urban cores, but not the kind of
- comprehensive data that I used here.
- Q. Did you consider using
- metropolitan statistical areas?
- A. The same answer. I did not.

- 1 That would be aggregating up. MSAs also
- split certain counties. It doesn't make
- sense to me to move up a level. The county
- 4 level is more granular than the MSA level.
- 5 Q. In certain places, though, the
- 6 county level may actually be larger than the
- MSA, right?
- A. That is true in urban areas.
- 9 In rural areas, MSAs include multiple
- counties. They're not precisely overlapping,
- 11 I know from having done some matching at some
- point, they're not easy to cross-walk.
- Q. Okay. So back to paragraph 83
- of your report. So you say as you just said
- that you used county-level ARCOS data on
- shipments of prescription opioids between
- 17 1997 and 2016, correct?
- A. Yes.
- 19 Q. But ARCOS actually doesn't have
- county-level data, does it?
- 21 A. The -- I believe the data are
- mapped to counties.
- Whereupon, Deposition Exhibit
- Rosenthal-22, Data Appendix, was
- marked for identification.)

- 1 BY MR. ROTH:
- Q. That's right. So let's look at
- 3 Exhibit 22, which is the data appendix that I
- believe you shared with Professors Cutler and
- 5 Gruber?
- A. That's right. As I mentioned,
- 7 the ARCOS data for me come through Compass
- 8 Lexecon.
- 9 Q. Okay. So we spoke yesterday
- about who helped you with your report, and it
- was Greylock McKinnon. Other than giving you
- the ARCOS data, did Compass Lexecon have any
- role in the preparation of your expert
- 14 report?
- A. No role in the preparation of
- my expert report, no.
- Q. And did you speak with anyone
- 18 from Compass Lexecon directly?
- 19 A. Yes, we talked about those
- meetings, and perhaps some of the calls,
- there were people from Compass Lexecon on
- those.
- Q. But in terms of your regression
- 24 analyses and running the Wald statistical
- tests, that was all Greylock and yourself;

- that was not Compass Lexecon?
- A. Yes, that's correct, my staff
- ³ ran these.
- 4 Q. Okay. So if we look at
- 5 Exhibit 22, turn to page 11, and it's a
- 6 section on the ARCOS prescription shipment
- ⁷ data.
- 8 Do you see that?
- 9 A. Yes.
- 10 Q. Do you know who prepared this
- document?
- A. I do not, no.
- Q. It was not you or your staff as
- 14 far as you know?
- 15 A. It was not me or my -- it
- 16 certainly was not me. I do not believe it
- was my staff.
- Q. So on the top of page 12, it
- 19 says: The Drug Enforcement Agency, DEA,
- provides data on shipments of prescription
- opioids over time and across geographies.
- This appendix describes the source of these
- data and the steps taken to process and set
- up the data for analysis.
- Do you see that?

- 1 A. Yes.
- Q. Then also on page 12, we'll get
- 3 to this later, but it shows the DEA drug
- 4 codes and names in the ARCOS data which are
- 5 at the molecule level.
- 6 A. That's right.
- 7 Q. And that was why you couldn't
- 8 separate out the Schedule IIIs, as we
- 9 discussed?
- 10 A. That's correct.
- 11 Q. And then if you turn to
- page 13, the next page.
- A. Yeah.
- Q. Sorry, it's actually on
- page 14. That's my errata.
- Do you see the section mapping
- shipments from three-digit ZIP codes to
- 18 counties?
- A. Yes, I do.
- Q. It says: As noted above, the
- most detailed geographic area reported in the
- public ARCOS reports is the three-digit ZIP
- code. Three-digit ZIP codes are based on the
- 24 first three digits of standard U.S. postal
- 25 ZIP codes. These areas typically, but not

- exclusively, span across more than one county
- and thus are not directly comparable to the
- 3 county level of data available for mortality,
- 4 crime and geographic -- I'm sorry, crime and
- 5 demographic and economic statistics.
- Do you see that?
- 7 A. I do.
- Q. And were you aware of that
- 9 issue?
- 10 A. I was at one level. I had
- forgotten that there was a cross-walk from
- three-digit ZIPs, which themselves, again,
- are geographic areas that vary in terms of
- 14 how big they are.
- Q. Do you know how Cuyahoga County
- compares to the three-digit ZIPs that are
- reflected in the ARCOS data for that area?
- 18 A. I'm sorry, I do not.
- Q. Do you know how Summit County
- compares to the three-digit ZIPs for that
- part of Ohio?
- A. No, I did not.
- Q. And if you look at page 15, it
- says: In order to link the ARCOS shipments
- data to the other county data, we have

- allocated shipments based on the weighted
- 2 average population of census block centroids,
- 3 center points that fall within each county
- 4 that a three-digit ZIP code crosses. And
- 5 then this means that when a three-digit ZIP
- 6 code crosses county boundaries, we use the
- 7 population at the census block level to
- 8 estimate the share of population across
- 9 counties for the three-digit ZIP.
- Do you see that?
- 11 A. I do.
- 12 Q. An underlying assumption to
- this approach is that the shipments per
- capita within a three-digit ZIP code are the
- same across census blocks.
- Do you see that?
- 17 A. Yes.
- Q. And when it says "we have
- allocated," do you know who did that work?
- 20 A. Compass Lexecon, but I don't
- know who in particular.
- Q. And did you do anything to test
- 23 Compass Lexecon or whomever's underlying
- 24 assumption that shipments per capita within a
- three-digit ZIP code are the same across

- 1 census blocks?
- A. I did not, no. I don't think
- it's possible to do that with these data
- because there aren't census block level data
- 5 in ARCOS.
- Q. And then they explain their
- 7 methodology below with the mathematical
- 8 formula of how they allocated ARCOS drug
- 9 shipment totals to the counties based on
- population share?
- 11 A. That's right.
- Q. And that's not an analysis
- you've seen before?
- 14 A. I'm sorry, what do you mean?
- 15 I've seen this data appendix.
- 16 Q. Have you seen the analysis for
- how Compass Lexecon allocated ARCOS shipments
- to the counties?
- 19 A. I guess I don't know what you
- mean by "seen." I understand that they
- 21 allocated based on population using this
- formula, so have I seen the individual
- calculations, is that what you're asking?
- Q. Correct.
- A. No, I have not.

```
1
            Ο.
                   Okay. And you would agree that
2.
     just because a product is shipped to certain
3
     counties does not mean it's consumed there?
4
                   MR. SOBOL: Objection, asked
5
            and answered.
6
            Α.
                   I think as explained in -- in
7
     the Cutler report, and Gruber may have said
8
     it also, to the extent that shipments are
9
     moving from one county to another, this
10
     regression methodology will -- it will just
11
     contribute to noise essentially in the
12
     regression.
13
                   So it's -- that -- the fact
14
     that there may be understatement of shipments
15
     in Ohio -- I think that's the premise here --
16
     because there's overstatement somewhere else
17
     because they moved from one place to another,
18
     that itself won't bias this analysis. It may
19
     create some noise.
20
     BY MR. ROTH:
21
                   What is your basis for thinking
22
     there's an understatement of shipments to
23
     Ohio in the ARCOS data?
24
                   Well, again, it's really
25
     reading Cutler and Gruber's reports and the
```

- notion of the -- I guess it was the
- Oxy Express, so the shipments go to Florida,
- but they ultimately end up in Ohio and
- 4 Kentucky and places like that.
- 5 Q. And have you done any analysis
- 6 as to how the Oxy Express influenced
- 7 consumption of prescription opioids in Ohio?
- A. No, I have not.
- 9 Q. Do you agree that the census
- data on population is not necessarily
- connected to where opioids are consumed?
- 12 A. Allocating shipments based on
- population is a reasonable approach, and I
- think, you know, as they say in footnote 24,
- this is -- it's very common that we make such
- geographic cross-walks just because the way
- data are presented. It's a reasonable basis
- for allocating shipments in my opinion.
- 19 Q. I understand you think it's a
- reasonable basis. I'm not asking that.
- I'm just asking the factual
- question. Where the population is shown in
- the census data is not necessarily correlated
- to where the shipments are consumed?
- MR. SOBOL: Objection.

```
1
            Α.
                   Well, it almost --
2.
                   MR. SOBOL: Asked and answered.
3
            Α.
                   It almost certainly is
4
     correlated because you need peoples -- people
5
     to have consumption, but exactly what the
6
     relationship is, I can't say for sure. But
7
     again, it almost surely is a major factor in
8
     determining where the consumption is. It may
9
     not be perfectly correlated.
10
     BY MR. ROTH:
11
                   And people don't necessarily
            Ο.
12
     consume prescription opioids in their homes,
13
     right?
14
                   MR. SOBOL: Objection.
15
            Α.
                   Well, I don't think that that's
16
     the -- that's the relevant question for my
17
     analysis. Again, I'm really looking at what
18
     factors predict shipments here, so wherever
19
     people consume them.
20
     BY MR. ROTH:
21
                   But you understand that your
22
     analysis is feeding into Professor Cutler's
23
     analysis and Professor McGuire's analysis who
24
     are trying to compute harms and damages
25
     occurring within Summit and Cuyahoga County?
```

- 1 A. It's true, but the way my
- indirect analysis feeds into Professor
- 3 Cutler's analysis is in the aggregate.
- Q. If you turn to paragraph 84,
- 5 that lists, I believe, all the variables you
- 6 include in the indirect model; is that
- 7 correct?
- 8 A. Yes.
- 9 Q. So you've got three categories,
- demographic, economic and healthcare
- variables.
- 12 A. That's right.
- Q. Let's take those one at a time.
- So the demographic variables
- you include are essentially gender, male
- versus female?
- A. Yes.
- 18 Q. The percent in different age
- groups set out in your report as to how you
- divided them, it looks like into five
- different age -- six different age group --
- five different age groups?
- A. Sure. Sorry, these are just
- standard census categories.
- Q. Okay. Another demographic

- factor you included is the percent of the
- population that is white, black and
- 3 Hispanic --
- 4 A. Yes.
- 5 Q. -- so race.
- 6 And then the share of the
- 7 population in four different education
- groups, correct?
- 9 A. Yes.
- Q. And the percent of the county
- identified as urban, correct?
- 12 A. That's right.
- Q. And are all of those census
- 14 categories?
- A. I believe so, yes. I think
- they all come from the ASEC that we talked
- about.
- Q. Okay. And then in the second
- category, economic variables, you included
- the unemployment rate?
- A. Yes.
- Q. You included
- employment-to-population ratio?
- 24 A. Yes.
- Q. You included the distribution

of employment by major industry sector? 1 2. Α. Yes. 3 You included median household Ο. 4 income? 5 Α. Yes. You included the poverty rate? 6 Ο. 7 Α. Yes. And you included the county's 8 Ο. population? 10 Α. Yes. 11 And then for healthcare, you Q. 12 only included two variables, correct? 13 MR. SOBOL: Objection. 14 You can answer. 15 Yes, I included two healthcare Α. 16 variables. 17 BY MR. ROTH: 18 And one was the percentage of the population without insurance, correct? 19 20 Α. That's correct. 21 And the second variable is the 22 number of cancer deaths, correct? 23 Α. That's correct. 24 Why did you include a variable 25 to account for the percentage of the

- population without insurance?
- A. I included that variable
- because I thought that there might be
- 4 relatively widespread coverage differences
- 5 across counties and that that might explain,
- 6 as I think we talked a little bit about
- yesterday, the extent to which people go to
- 8 the doctor and therefore get a prescription,
- 9 and also, their likelihood of filling a
- prescription.
- 11 Q. Insurance coverage, though, is
- not a variable you included in your direct
- model?
- 14 A. That's correct. And I'm sure
- we'll continue to come back to this, but the
- 16 cross-sectional variation, insurance coverage
- is a lot more substantial across counties
- than it is over time.
- 19 Q. In your -- what I'll call
- thought experiment, which we'll talk about in
- 21 a minute, you include as potentially
- medically allowable prescriptions, surgery
- and trauma; is that right?
- A. Yes. I guess we'll discuss the
- right words to describe that, but yes, so as

- the potentially appropriate uses, something
- like that I think is what I say, that
- 3 surgical and trauma conditions, yes.
- 4 Q. But in your indirect model you
- don't have any variables for either surgery
- 6 or trauma?
- A. I do not, no.
- Q. And why is that?
- 9 A. Well, the data from the
- healthcare utilization project that we
- will -- we'll talk about later, those cannot
- be disaggregated. There are some state-level
- data, but they're considered to not be
- reliable for that purpose, so those are
- ¹⁵ national data only.
- And ultimately, the trends in
- those -- sorry, wrong question, I was
- answering the direct model.
- And ultimately, those factors,
- the numbers there, I don't believe that we
- have reliable estimates across counties over
- the entire time period.
- Q. I'm a little confused because
- you just said the surgery and trauma
- 25 figures --

- 1 Α. Yeah. 2. -- cannot be disaggregated, but Ο. 3 I thought in your last section you have a 4 disaggregation of potentially appropriate 5 MMEs for Summit and Cuyahoga that includes 6 trauma and surgery. 7 Yeah, the HCUP data, those data 8 are not at the county level. The other data 9 are at the county level, the Area Health
- 10 Resources File. So I was distinguishing
- 11 between those two.
- 12 And in general, you can see,
- 13 when we get to the appropriate uses, that
- 14 the -- those trend downwards, and so even if
- 15 we were to include those in the model and
- 16 they had a cross-sectional relationship, it
- 17 would not cause the indirect estimate to be
- 18 increasing.
- 19 But you didn't actually include
- 20 those in the model?
- 21 I didn't, no. Α.
- 22 Did you consider any other Ο.
- 23 variables to include in any of the three
- 24 categories, demographic, economic or
- 25 healthcare, in your indirect model, aside

- from the ones we've discussed?
- A. No, these are the variables --
- these variables are based on previous
- 4 literature, all of those demographic and
- 5 socioeconomic variables come from an
- 6 assessment of what has been shown to be
- 7 associated with opioid use.
- Q. And what literature assessing
- the variables associated with opioid use are
- you relying on?
- 11 A. Well, I don't think I have a
- citation in here, so I don't know a specific
- paper as I sit here. Again, these are --
- these are variables that economists studying
- opioid use have used from the census data.
- This is the source of data that
- have been used by researchers. I think most
- of that literature is cited in Professor
- 19 Cutler's report.
- Q. Okay. And is -- was the list
- of variables you would use in your indirect
- model a subject of discussion between
- yourself and Professor Cutler?
- A. I can answer that if counsel
- were present?

```
1
                   MR. SOBOL: Well, yes or no.
 2.
            Α.
                   Yes.
 3
     BY MR. ROTH:
 4
            Q.
                   So if you look --
                   MR. SOBOL: You got so used to
 5
 6
            just running on that you forgot you
 7
            could answer yes or no.
 8
     BY MR. ROTH:
 9
                   If you look at page 25 of
            Q.
10
     Exhibit 22.
11
            Α.
                   Okay. This is the data
12
     appendix?
13
            Ο.
                   Yes.
14
            Α.
                   Yeah. The Table 2?
15
            Ο.
                   Yes.
16
                   So this is a table that
17
      reflects economic and demographic variables
18
     with data sources and years reported.
19
                   Uh-huh.
            Α.
20
                   And this is the shared
            Q.
21
     appendix, but I assume these are the
22
     variables we've been discussing that you used
23
      in your indirect regression?
24
            Α.
                   Yes, they are.
25
            Q.
                   Okay. So if you look at
```

- several of the rows, there's a shaded gray
- bar that says Interpolated.
- Do you see that?
- 4 A. Yes, that's right.
- 5 Q. And what does that mean?
- A. Well, some of the variables
- 7 come only from the decennial census, so we
- 8 have them for every ten years, so a linear
- 9 interpolation was used between those ten-year
- 10 points.
- 11 Q. And how do you know it was a
- linear interpolation?
- 13 A. Well, I should read more
- 14 closely. I believe it is a linear
- interpretation, but my memory is not to be
- 16 trusted.
- Q. You know what, you're right.
- Actually, it says that at the bottom of the
- chart. Interpolated values are a linear
- interpolation between the preceding and
- following measured value.
- 22 A. Someone should do something
- about that font size.
- Q. Who performed the linear
- interpolation on the census data for the

- variables that were interpolated?
- A. I do not know the specific
- individual. These were constructed by
- 4 Compass Lexecon.
- 5 Q. Did you consider picking a year
- 6 where you did not need to do interpolation,
- your such as the year 2000, as your baseline?
- 8 A. No, I did not consider that.
- 9 Q. Are you using interpolated
- values for these variables in your 1997
- 11 baseline?
- 12 A. Yes, I am.
- 13 Q. Is it possible the interpolated
- variables affect the baseline estimated
- relationship between the explanatory
- variables and shipments per capita per day?
- MR. SOBOL: Objection to form.
- 18 A. These socioeconomic and
- demographic variables change very slowly, and
- I believe the linear interpolation method is
- entirely appropriate.
- I do not believe that they are
- likely to cause any impact on my analysis,
- but if any, they would be a source of
- mismeasurement, which would dampen -- which

- would basically cause noise, but not bias.
- BY MR. ROTH:
- Q. Have you studied the linear
- 4 interpolation that was done and how it might
- 5 impact your analysis?
- A. Well, I'm not exactly sure how
- one would study such a thing. Again, we
- 8 undertake the interpolation because those
- 9 data were not captured in those years, so
- there's not a gold standard to compare the
- linear interpolation to.
- Q. But what you could do is pick a
- year where no interpolation were needed and
- compare the results from that year, say 2000,
- against '97 with the interpolation?
- MR. SOBOL: Objection.
- A. Well, as we discussed earlier,
- my effort was to undertake the
- cross-sectional analysis in a year that was
- unaffected by the alleged misconduct, and
- 1997, while imperfect, is a bit closer to
- that.
- 23 2000 would be a time period in
- which the alleged misconduct was well under
- way, so I did not consider such an analysis.

1 BY MR. ROTH: 2. And when you say the alleged Ο. 3 misconduct was well under way in 2000, that's 4 based on your assumption that it started in 5 1995 as opposed to a review of actual promotion that occurred between '95 and 2000? 6 7 MR. SOBOL: Objection. 8 Well, again, I am assuming that Α. plaintiffs' counsel will prove their case. 10 As you know, there's quite a bit of evidence 11 that I can't evaluate from a legal 12 perspective that I can see as a layperson 13 that suggests marketing messages related to 14 opioids were, in fact, dampening the sense of 15 the addictive properties of these drugs. 16 Whether or not that's unlawful 17 I can't say, but I can certainly see that 18 what the allegations describe was happening 19 during this period. 20 BY MR. ROTH: 21 Do you understand -- well, 22 strike that. Let me ask it a different way. 23 Does your model assume that 24 unlawful detailing occurred even if that

detailing were solely based on FDA-approved

25

labels or marketing materials? 1 2. MR. SOBOL: Objection, asked 3 and answered. 4 Α. Well, you're asking me to 5 assume a hypothetical in that case, I think, 6 that all marketing was based on FDA-approved 7 labels. 8 BY MR. ROTH: 9 I don't think so. I think what Ο. 10 I'm asking is your model treats all of 11 defendants' promotion as unlawful based on 12 the assumption that you made based on the 13 instruction of counsel, correct? 14 MR. SOBOL: Objection, asked 15 and answered. 16 Yes. I have been asked to Α. 17 assume that plaintiffs will prove that in 18 sum, defendants' marketing was unlawful. 19 BY MR. ROTH: 20 Okay. And if, in fact, a Q. 21 defendant or subset of defendants only 22 promoted using FDA-approved labeling and/or 23 FDA-approved marketing materials, how does 24 your model address that? 25 MR. SOBOL: Objection, asked

```
and answered.
```

- A. I think you're asking me a
- legal question, so I do not know whether such
- 4 a hypothetical would have -- would exclude
- 5 the possibility that the conduct was unlawful
- in some other way. I don't know.
- 7 BY MR. ROTH:
- Q. Just assume my hypothetical is
- 9 so, okay? Don't fight the hypothetical.
- 10 If for a given defendant it is
- proven that all promotion was solely based on
- FDA-approved labeling and FDA-approved
- marketing materials, your model still
- includes those promotional contacts in
- calculating the aggregate impact, correct?
- MR. SOBOL: Objection, asked
- and answered.
- 18 A. I guess I'm trying to
- understand. We've been talking about my
- indirect model, which does not include a
- 21 measure --
- 22 BY MR. ROTH:
- Q. Yeah. I'm back to the direct
- for this question. I'm back to direct for
- this question.

```
1
                   Going back to --
            Α.
 2.
                   Let me reask it because we're
            0.
 3
     talking over each other.
                   If for a given defendant it is
 4
 5
     proven that all promotion was solely based on
 6
     FDA-approved labeling and FDA-approved
 7
     marketing materials, your direct model still
     includes that defendant's promotional
 8
 9
     contacts in calculating the aggregate impact,
10
     correct?
11
                   MR. SOBOL: Objection, asked
12
            and answered, misstates prior
13
            testimony.
14
                   I do not know whether a
            Α.
15
     hypothetical in which the marketing were
16
     based solely on FDA-approved materials is in
17
     any way in contradiction to the assumption
18
     that that marketing can be proven unlawful.
19
     That is a legal question, the answer to which
20
     I do not know.
21
     BY MR. ROTH:
22
            Ο.
                   Now if you turn to paragraph 81
23
     of your report, and now we're back to the
     indirect model.
24
```

In paragraph 81, you say:

25

- 1 Based on these estimates of the relationship
- between the economic, demographic and
- 3 healthcare characteristics of counties and
- 4 opioid sales before the opioid epidemic took
- 5 hold, the model can be used to predict opioid
- 6 sales using only changes in the X-i variables
- 7 over time.
- 8 Do you see that?
- 9 A. I do.
- Q. And then you say: A modified
- version of this approach incorporates an
- estimated secular trend also using data from
- the pre-misconduct period.
- Do you see that?
- 15 A. I do.
- 0. So what is a secular trend?
- A. Secular trend here, it's
- 18 literally a linear trend that I calculate
- using sort of a long series of pre-alleged
- ²⁰ misconduct data.
- Q. That's based on the growth rate
- in opioid sales from 1980 to 1995?
- A. That's correct.
- O. And that trend would include
- obviously only the molecules that were

- approved and sold at that time, correct?
- A. By definition, yes.
- Q. And I think that would mean it
- 4 would include morphine, pethidine, oxycodone,
- fentanyl and hydromorphone.
- Does that sound right?
- 7 MR. SOBOL: Objection.
- A. I am not a hundred percent sure
- 9 so I would have to actually look at the INCB
- data.
- 11 BY MR. ROTH:
- 12 Q. So do you know which molecules
- are included in the secular trend and which
- 14 are not?
- 15 A. The data from the INCB are like
- the ARCOS data, they're at the molecule
- level. I just -- as I sit here, I can't
- remember, but the analysis was done to
- include the analogous products, recognizing
- that there are new entrants that happen after
- ²¹ 1995.
- Q. Do you know whether or not the
- 23 INCB data from 1980 to 1995 includes
- 24 hydrocodone?
- A. I do not as I sit here.

```
1 Q. Do you know whether the INCB
```

- data from 1980 to 1995 includes propoxyphene?
- A. I -- as I sit here, I do not.
- 4 I'm trying to remember if it's actually in my
- 5 Appendix D.
- Q. If it is, I'm happy to look at
- 7 it. I don't --
- A. Yeah.
- 9 Q. -- know if it is or not. It
- may also be in that data appendix I gave you.
- But so we don't get bogged down
- 12 on it --
- A. Sure.
- Q. -- it's fair to say, whatever
- drugs are listed in the INCB data from 1980
- to 1995 are included in the secular trend,
- 17 correct?
- A. I believe so, yes.
- Q. And any drugs that are not
- listed in that data are not included in the
- secular trend?
- A. I think that's right, yes.
- Q. And if any of the opioids not
- included in the secular trend grew at a
- faster rate than those included, your

- indirect model would not fully account for
- the intended market-expanding effects of
- promotion for those molecules?
- 4 MR. SOBOL: Objection.
- A. Again, adding the secular trend
- in my opinion is very conservative here to
- begin with. My intent was to capture all the
- 8 relevant molecules, basically those that map
- 9 to the market that I'm looking at post 1995,
- recognizing that there are changes over time.
- And so this secular trend in my
- indirect model is intending to capture
- defendant -- non-defendant, sorry,
- promotion -- that's an important verbal
- errata.
- So as already, because some of
- the defendants may be involved in that early
- data, they may be picking up some of the
- alleged misconduct, if some of it occurs
- before 1995, I think I'm not as concerned
- 21 about underestimating that trend.
- 22 BY MR. ROTH:
- Q. But just so I understand, if
- the opioids omitted from the secular trend
- grew at a faster rate than the included

```
1 molecules, your indirect model would fail to
```

- 2 account for the intended market-expanding
- effects of non-defendant promotion?
- 4 MR. SOBOL: Objection, asked
- 5 and answered.
- A. Again, I believe that I
- included the molecules that were appropriate
- for inclusion. I don't know that there are
- 9 any that should have been included that
- weren't.
- My intention was to capture the
- set of molecules that -- that were similar --
- were basically the available alternatives
- over that period to -- as opioid analgesics.
- And if there -- I guess if there were any
- that are omitted, I could identify those and
- adjust the trend if need be.
- 18 BY MR. ROTH:
- 19 Q. Before your post-estimation
- secular trend and aggregate price
- 21 adjustments, are your predicted values of
- shipments per capita per day influenced only
- by changes in the demographic, economic and
- healthcare explanatory variables?
- A. I don't know what you mean by

- 1 "only," but the -- as you can see in Table 4,
- there are a number of significant
- 3 relationships across those demographic,
- 4 socioeconomic and healthcare variables, and
- 5 there are about 20 variables included there
- 6 in total.
- 7 Q. And since you've directed me to
- Table 4, what does it mean, "no obs," is that
- 9 number of observations, 404?
- 10 A. Yes, I'm sorry. We're not very
- generous with our shorthand, are we? Yes,
- that's the number of observations.
- Q. What does that mean exactly?
- 14 A. That's the number of counties
- in the sample.
- Q. Okay. And the R-squared of the
- indirect model is 33%?
- 18 A. That's correct.
- Q. Which is not 99.6%.
- A. As I note in the chapter,
- cross-sectional regressions never have the
- same R-squared as time series analysis.
- Q. Did you consider the prediction
- intervals for your predicted shipments per
- 25 capita per day?

1 What do you mean by the Α. 2. prediction intervals? 3 Ο. Yeah. Did you consider upper 4 and lower bounds for your predictions? You mean by setting the 5 Α. 6 independent variables to extreme levels? I'm 7 still not sure what you're talking about. 8 Yeah, I think that's right. Ο. 9 I did not look at trying to Α. 10 predict out of sample. I'm interested in 11 using these variables to be able to then take 12 the trends in the underlying demographic, 13 socioeconomic and healthcare factors and 14 predict forward in the ranges that those 15 variables hold. So I did not look at extreme 16 values. 17 Ο. Okay. If you look at 18 paragraph 88, you talk about how you adjusted 19 for price impact in the indirect model? 20 Α. Yes. 21 And then you say: There's 22 little county-level variation in opioid 23 prices so this variable does not appear in 24 the cross-sectional model, despite the fact 25 that my direct model shows a small but

- significant negative effect of price on sales
- 2 over time.
- Do you see that?
- 4 A. I do.
- 5 Q. And what is your basis for the
- 6 statement that there's little county-level
- 7 variation in opioid prices?
- A. That's based on my knowledge
- 9 and experience as a health economist who has
- done a lot of work on pharmaceutical pricing.
- 11 As you may know, pharmaceutical manufacturers
- report list prices, and those list prices are
- the basis for retail transaction prices.
- 14 O. AWP?
- A. AWP.
- Q. Have you done any analysis
- specific to opioid products and potential
- price variation across counties?
- 19 A. I have not calculated that
- variation in this matter, no.
- Q. And in your direct model you
- 22 acknowledge there is a small but significant
- downward effect of price on sales over time?
- A. Yes, which is why I adjust for
- it here.

- Q. And how do you adjust for it?
- That's how you described it in paragraph 88,
- by changing the estimated coefficient on the
- 4 drug price index?
- 5 A. So I used the estimated
- 6 coefficient from the direct model and then
- the trend in prices in order to project that
- 8 price effect.
- 9 Q. So you use your direct model's
- output for the price coefficient, and then as
- you say, adjust for the trend in prices?
- 12 A. That's correct.
- Q. Okay. Can we agree generally
- that omitted variables can cause bias in
- regression analyses?
- 16 A. The concern about omitted
- variables is a ubiquitous one in any
- econometric analysis. I believe that I have
- appropriately captured the most important
- variables in my analysis.
- Q. And do you agree that to the
- extent that other factors not modeled in the
- 23 baseline regression contributed to increases
- in opioid shipments, the indirect approach
- has the potential to overstate the impact of

```
1 promotion on shipments?
```

- MR. SOBOL: Objection, asked
- and answered.
- 4 A. I'm not aware of any variables
- 5 that should be in the model that would make a
- 6 substantial effect here. If such a variable
- 7 existed, it could affect the calculations in
- 8 the way that you suggest.
- 9 BY MR. ROTH:
- Q. Okay. You did not include a
- variable reflecting the number of military
- veterans in the counties, did you?
- A. No, I did not.
- Q. Do you agree the number of
- veterans in a county could increase the
- amount of MMEs sold?
- 17 A. I don't know as I sit here
- whether that's a reasonable thing to posit.
- 19 Q. You've not looked at any
- literature as to whether veterans require
- more opioids than other citizens?
- A. I have not, and you have to
- keep in mind that there are a number of other
- variables in the model that will be
- correlated with the number of military

- veterans or any other sociodemographic group,
- if that's appropriate to call military
- yeterans a sociodemographic group, such as
- 4 the educational distribution, ages, those
- 5 things may well pick up some effects, if any
- 6 exist.
- 7 Q. Okay. But you didn't include
- 8 veterans specifically?
- 9 A. I did not.
- 10 Q. You did not include a variable
- reflecting the number of doctors in the
- county, correct?
- 13 A. I did not include a variable
- 14 reflecting the number of doctors in the
- county.
- Q. Can we agree that the number of
- doctors in a county can affect the amount of
- 18 MMEs prescribed and sold in that county?
- 19 A. It's possible, but again, the
- variables that are included in my model I
- believe would be correlated with the number
- of doctors in a county, so rurality, for
- example, will be correlated with the number
- of doctors, the percent uninsured will be
- correlated with the number of doctors, and I

- believe the included variables in my model
- are sufficient to pick up those effects.
- Q. Okay. You did not include a
- 4 variable reflecting the number of hospitals
- 5 in a county?
- 6 A. I did not include a variable
- 7 reflecting the number of hospitals in the
- 8 county, and again, I believe the demographic
- 9 and socioeconomic variables in my model will
- be correlated with the presence of hospitals,
- and therefore I am not concerned about the
- bias from that exclusion.
- Q. Would you agree the number of
- hospitals in a county could influence the
- amount of MMEs prescribed and sold in that
- 16 county?
- 17 A. I believe as a factor it could
- have some effect, and that the variables that
- 19 I include in my model will be sufficiently
- correlated with that, that the omission of
- the number of hospitals will not bias my
- 22 results.
- O. You did not include a variable
- reflecting the number of pharmacies in a
- county?

- 1 A. I did not include a variable
- 2 reflecting the number of pharmacies, and like
- any other measure of economic activity, I
- believe that will be strongly correlated with
- 5 the socioeconomic variables that I do include
- in my model.
- 7 Q. Would you agree that the number
- 8 of pharmacies in a county may increase the
- amount of MMEs shipped to that county?
- 10 A. Ignoring the fact that the
- other factors that I include may well account
- for that effect as an independent matter, the
- 13 number of pharmacies may affect the number of
- shipments in a county.
- Q. Did you include a variable on
- the incidence of cancer in a county?
- 17 A. I included cancer deaths rather
- than cancer incidence.
- Q. And is it your view that cancer
- deaths is a sufficient proxy for the
- incidence of cancer?
- A. Well, of course, cancer deaths
- will be substantially correlated with cancer
- incidence, and I included cancer deaths on
- the premise that opioids are indicated for

- end-of-life cancer treatment.
- Q. Do you understand that opioids
- may be indicated for cancer pain even if it's
- 4 not at end of life?
- 5 A. I understand that according to
- 6 clinical experts there are certain cases
- 7 where opioids may be indicated for cancer
- ⁸ pain.
- 9 Q. Do you agree that cancer
- incidence may increase the amount of MMEs
- shipped to a county?
- A. Actually, I was -- it is
- possible that cancer incidence does correlate
- with the number of MMEs per county, but very
- unlikely to me that adding cancer incidence
- to a model that has cancer deaths would
- contribute anything to explaining the
- variation in county-level shipments.
- 19 Q. You did not include a variable
- reflecting the number of individuals eligible
- for a pharmacy benefit through their insurer
- in a county?
- A. I did not include a variable
- reflecting the number of individuals eligible
- for a pharmacy benefit in the county. Again,

- 1 I believe that in particular, the percent
- uninsured will summarize the accessibility to
- 3 coverage and that adding the pharmacy benefit
- 4 piece will contribute very little given the
- more than 90%, I think more than 95% of
- 6 people who have insurance also have a
- 7 pharmacy benefit.
- 8 Q. But as we spoke about
- 9 yesterday, the parameters of insurance
- 10 coverage including a pharmacy benefit can
- influence the prescription and utilization of
- opioids?
- MR. SOBOL: Objection.
- A. While it may be true for an
- individual patient, you can see that my
- percent uninsured variable, is not
- statistically significant in this model, so
- again, accounting already for the population
- characteristics, the socioeconomic
- characteristics of the county, percent
- uninsured, which is clearly the first order
- measure, does not add any -- anything to this
- model in terms of explanatory value, and so
- getting even more granular than that I
- believe would not change the model.

```
1
     BY MR. ROTH:
2.
                   You did not include a variable
            Ο.
3
     reflecting the existence or number of pill
4
     mills in a county.
5
                   I did not include a variable
            Α.
6
     reflecting the existence of pill mills.
7
     think to control for that does not make a lot
8
     of sense to me, given that I believe it's --
     that those may have been caused by the
10
     alleged misconduct.
11
                   Moreover, as with other
12
     variables not included of that supply side
13
     nature, I believe the socioeconomic variables
14
     are likely to explain a great deal of the
15
     variation in the existence of pill mills.
16
                   So is it your position that the
17
     manufacturers' promotion created the
18
     diversion of prescription opioids through
19
     pill mills?
20
                   MR. SOBOL: Objection to the
21
            form.
22
                   I have not offered that
            Α.
23
     opinion, but you asked me as to whether I
24
     would consider -- well, you asked me whether
```

I included pill mills and my first reaction

25

- is that I would not consider that to be an
- 2 appropriate variable to control for because
- it would essentially say, oh, yeah, this
- is -- this is expected. These pill mills are
- 5 expected, and only changes in opioid
- 6 prescribing outside of the pill mills would
- ⁷ be subject to recovery.
- 8 As I understand the
- 9 allegations, I would be very surprised if
- that would be an appropriate assumption.
- 11 Q. So in your view, you think the
- manufacturers should be responsible for the
- illegal prescription of opioids through pill
- 14 mills?
- MR. SOBOL: Objection.
- A. I think you've gone a little
- too far, but in my view, I wouldn't just
- include such a variable like that without
- better understanding exactly what plaintiffs
- intend to prove.
- BY MR. ROTH:
- Q. Do you agree that the existence
- of pill mills can increase the amount of MMEs
- shipped and utilized in a county?
- A. I believe that that is the

- 1 concern with pill mills. Perhaps by their
- derogatory name, that is my presumption, that
- they do, in fact, make opioids more available
- 4 than they otherwise would be.
- 5 Q. And more broadly, you did not
- 6 include any variable reflecting the existence
- or volume of illegal prescribing in the
- 8 county?
- 9 MR. SOBOL: Objection.
- 10 A. I do not have a variable on
- illegal prescribing in the county, no, I do
- not. And I would have the same concern about
- the extent to which that is to be considered
- an independent factor.
- 15 BY MR. ROTH:
- Q. You don't have a variable for
- formulary placement of opioids in the
- indirect model?
- 19 A. Did we not cover that?
- Q. We covered pharmacy benefits.
- A. Oh, I'm sorry. I have not
- included a formulary measure and I'm not
- sure -- entirely sure what you mean by that.
- But I would say again, given that the percent
- uninsured, which is the first order measure

- of coverage and accessibility is not
- statistically significant in my model, I
- would not anticipate a more nuanced measure
- 4 of the nature of coverage to affect my
- 5 results.
- 6 O. You did not include a variable
- 7 to account for the introduction of Medicare
- Part D in your model?
- 9 A. Well, the indirect model is a
- cross-sectional model of 1997, which is a
- 11 number of years in advance of Medicare
- Part D. And again, given that the percent
- uninsured seems to have no relationship in
- the cross-section to opioid use, then
- Medicare Part D would not play a role in the
- model.
- 17 Q. You did not include a variable
- for promotion by non-defendants in the model,
- 19 correct?
- A. My time trend, as I describe
- it, was intended to proxy for that, but --
- Q. Right. So you have a separate
- 23 secular trend.
- A. Yes.
- Q. You don't have it as a separate

- ¹ variable.
- A. That's right, it's not a
- separate variable, and that's why I include
- 4 the time trend.
- 5 Q. Are you aware that
- 6 non-defendant promotion accounts for
- 7 approximately 32% of the promotional contacts
- 8 in the IPS data, on a national level?
- 9 A. I'm hoping somewhere that's in
- my report. I'm willing to believe you. We
- certainly calculated that figure.
- 12 Q. Okay.
- 13 A. I just don't want to go back to
- the dreaded Table C.
- Q. Yeah, we may later, but we'll
- stop for now on there.
- A. Okay.
- Q. All of the variables we just
- discussed that you excluded from your
- indirect model are likewise excluded from
- your direct model?
- MR. SOBOL: Objection.
- A. The variables that we discussed
- do not appear in my direct model, and the
- direct model as an aggregate time series

- 1 model has different considerations in terms
- of what variables are appropriate to include.
- 3 BY MR. ROTH:
- 4 Q. And because you did not include
- 5 any of the excluded variables just discussed
- in your indirect model, you did not expressly
- measure the impact of those variables on the
- 8 sales of opioids in Cuyahoga or Summit
- 9 Counties?
- MR. SOBOL: Objection, asked
- and answered.
- 12 A. While that is tautologically
- true, it is the case, as I started when we
- were talking about omitted variable bias,
- that it's always possible to add more
- variable to a model, and that is not -- that
- is not good without limit.
- 18 BY MR. ROTH:
- Q. Well, I understand you don't
- want to add variables forever, but at what
- point does the number of variables in an
- indirect regression render the regression
- unstable?
- A. Well, it would depend on the
- correlation among those variables.

```
1
                   (Whereupon, Deposition Exhibit
2.
           Rosenthal-23, Case and Deaton
3
            Publication, was marked for
4
            identification.)
5
     BY MR. ROTH:
6
                   Okay. Let me mark as
7
     Exhibit 23 an article by Case and Deaton
     entitled Mortality and Morbidity in the 21st
8
     Century.
                   MR. ROTH: We're finding one
10
11
            for you.
12
                   (Comments off the stenographic
13
           record.)
14
                   MR. SOBOL: Sounds like a
15
            fairly narrow topic for a paper.
                   MR. ROTH: Why don't we take a
16
17
           quick break. We'll look for the copy.
18
                   THE WITNESS: Okay.
19
                   THE VIDEOGRAPHER: The time is
20
            10:16 a.m., we're now off the record.
21
                   (Discussion off the record.)
22
                   THE VIDEOGRAPHER: The time is
23
            10:16 a.m. We're back on the record.
     BY MR. ROTH:
24
                   That's pretty efficient.
25
           0.
```

- 1 A. That was very efficient.
- Q. So do you have the Case and
- Deaton article in front of you?
- 4 A. I do.
- Q. And if you look at page 444.
- 6 A. These economics articles are
- 7 very long.
- Q. I think you cite this article
- 9 in your report, do you not?
- 10 A. I think I do, yes.
- Q. Okay. Page 444, there's a
- comment from a friend.
- Do you see that?
- 14 A. I do.
- Q. And that's Professor Cutler,
- who is a co-expert with you and your
- 17 colleague at Harvard?
- 18 A. Yes, that's correct.
- Q. And so if you look at his
- comments on the next page, 445, starting in
- the middle of the page where he's talking
- about the article, he says: Their overall
- suggestion is very much in the tradition of
- ?mile Durkheim: People despair when their
- material and social circumstances are below

- what they had expected. This despair leads
- people to act in ways that significantly harm
- their health. This may have a direct impact
- 4 on death through suicide or an indirect
- 5 impact through heavy drinking, smoking, drug
- 6 abuse, or not taking preventative medications
- ⁷ for conditions such as heart disease. At
- 8 root is economic and social breakdown. This
- 9 explanation is certainly correct.
- Do you see that?
- 11 A. I do.
- Q. And what variables in your
- indirect model address the despair points
- that Professor Cutler is talking about?
- 15 A. Professor Cutler and Case and
- Deaton, they're talking about mortality.
- They're not talking about the use of opioids.
- Q. Well, except that he says that
- despair can lead people to abuse drugs.
- A. Yes, but it's quite a bit
- different. So they're talking about the
- mortality effects, which go beyond the use of
- drugs.
- As we've discussed somewhat
- over the last day and a half, the use of

- opioids in and of itself doesn't lead
- everyone to die from an overdose. There's
- tolerance and addiction, and all along that
- 4 chain, there are different factors that may
- 5 contribute to who actually dies of an
- overdose. So this -- this paper is really
- trying to get at the mortality results.
- And moreover, the socioeconomic
- yariables included in my model have much to
- do with this idea of the expected material
- and social circumstances, has to do with
- employment, whether people are in the labor
- force. All of those socioeconomic variables
- capture those factors.
- Q. But you don't include any
- variable, for example, on the incidence of
- depression in the counties?
- MR. SOBOL: Objection.
- 19 A. I do not include a variable on
- the incidence of depression. I have no
- reason to believe that that would predict
- opioid use.
- BY MR. ROTH:
- Q. You don't include any variable
- on the incidence of alcoholism in the

```
1
     counties?
2.
            Α.
                   I do not include a variable on
3
     the incidence of alcoholism, nor would I
4
     expect it to predict opioid use.
5
                   You don't think that alcohol
            Ο.
6
     use is correlated with opioid use?
7
                   Whether individuals who are
8
     likely to use opioids have some of the same
9
     personal characteristics as those
10
     individuals, that may well be true. But my
11
     demographic and socioeconomic factors are
12
     also capturing those underlying issues that
13
     may be, according to this notion, that the
14
     economic status of people is really what's
15
     driving the addiction tendencies, and those
16
     are the variables that I include in my model.
                   And similarly, you don't
17
            Q.
18
     include any variable in your -- either of
19
     your regression models related to drug abuse
20
     in the counties?
21
                   MR. SOBOL: Objection.
22
                   If you think about my indirect
            Α.
23
     model, predicting shipments to have drug
24
     abuse on the right-hand side would make very
```

little sense if the shipments caused the drug

25

```
1
     abuse.
2.
     BY MR. ROTH:
3
                   Well, there are drugs other
4
     than opioids in the world that are abused,
5
     right?
6
                   That may be true. Again, as a
           Α.
7
     broader matter, the demographic and
8
     socioeconomic variables that I do capture in
     my model are essentially the way Case and
10
     Deaton look at this as well as these being
11
     the predictors of ultimately what contributes
12
     to mortality.
13
                   MR. ROTH: Okay. Why don't we
14
            take another quick break.
15
                   THE WITNESS: Okay.
16
                   THE VIDEOGRAPHER: The time is
17
            10:21 a.m. We're now off the record.
18
                   (Recess taken, 10:21 a.m. to
19
            10:34 a.m.)
20
                   THE VIDEOGRAPHER: The time is
21
            10:35 a.m., and we're back on the
22
            record.
23
     BY MR. ROTH:
24
           Q. So sticking with your indirect
25
     model.
```

```
A. Okay.
```

- 2 Q. So we talked about a couple of
- times now how because the ARCOS data is at
- 4 the molecule level, you couldn't back out the
- 5 Schedule III opioids; is that right?
- 6 A. That's right. In those two
- 7 molecules that have a mix, right?
- Q. And your report says you don't
- 9 believe this impacts the model because it
- affects only less than 2?% of shipments, and
- then you further clarified actually that it's
- less than 1%.
- Did I hear that right?
- A. Right. So it's less than 2?%
- of shipments in those molecules -- I'm
- actually trying to look for the text. Do you
- have that paragraph?
- Q. It's paragraph 83.
- 19 A. Okay, great. Thank you. Less
- than 2?% of the shipments in those molecules
- that have a mix of Schedule II and Schedule
- III, and that's hydrocodone and codeine, I
- believe, are the two molecules that are
- 24 relevant.
- Q. And did you test how removing

- all of the Schedule III opioids from the
- 2 ARCOS data would impact your model?
- A. I don't believe so, no. I
- 4 mean, I assume what you mean is overremoving
- 5 since in the ARCOS data I couldn't
- 6 distinguish, but removing the molecules that
- have any Schedule III, is that what you're
- 8 asking?
- 9 Q. Right?
- 10 A. Yeah. That, I did not test.
- Q. And we established you used
- 12 1997 as your baseline, right?
- 13 A. That's correct.
- Q. So I assume your assumption is
- that the relationship between demographic,
- economic and healthcare variables for 1997
- holds for all future years?
- 18 A. That is the basic assumption of
- the indirect model in general, is that the
- cross-sectional relationships are stable, and
- just the variation in those variables changes
- over time.
- Q. Do you know what the
- rescheduled Schedule III opioids were as a
- percentage of sales in 1997?

- 1 A. When you say rescheduled,
- you're just talking about hydrocodone?
- Q. Well, let me reask the
- 4 question.
- 5 A. Sure.
- Q. Do you know what the percentage
- of sales Schedule III opioids were in 1997?
- A. If -- I'm sorry. I don't know
- 9 that I understand the question because I know
- the answer to a version of that question,
- which I think is the relevant one.
- The percentage of the included
- molecules that are Schedule III that I can't
- pull out is 2?%.
- 15 O. In 1997?
- 16 A. In 1997, yes.
- Q. Okay. What about the rest of
- the Schedule III, that later became Schedule
- 19 II on the rescheduling, what was their
- percentage of sales in 1997?
- A. So now we're talking about
- 22 hydrocodone rescheduling?
- Q. Correct.
- A. I have not assessed that.
- 25 Again, as we talked about yesterday, I've

- been asked to assume that hydrocodone should
- be included in my measure of impact for the
- 3 whole period.
- 4 Q. And how would it affect the
- 5 results of your indirect regression if the
- 6 percentage of Schedule III molecules in the
- 7 sales data changes over time?
- A. I don't think it would affect
- 9 the results. I mean, I think, again, to the
- extent that it has an effect, it's a -- it's
- 11 a level effect.
- For such a small quantum that's
- in my analysis, the Schedule III drugs, it's
- just next to impossible that it has any
- effect on the coefficients. It overstates
- the set of molecules, the number of MMEs, and
- that effect I know also is small. It's less
- than 1% of MMEs.
- In terms of the rescheduling of
- hydrocodone, I haven't quantified that, so as
- I sit here, I can't tell you. Again, I
- believe if it has an effect and if it's
- deemed, for example, that hydrocodone should
- only be included when it was Schedule II and
- not when it was Schedule III, then those MMEs

- would just be backed out of the levels.
- Q. Okay. If we look back at
- Table 5 on page 61.
- 4 A. Yes.
- 5 O. How does the volume of MMEs
- 6 that you derive from your indirect regression
- 7 compare to the volume of MMEs you derived in
- 9 your direct regression?
- A. The total volume, because I'm
- looking at the large counties here, they're
- about two-thirds of the national total, so it
- essentially should be about two-thirds.
- 13 Again, these are annual numbers and I use
- monthly numbers as inputs into my direct
- analysis.
- Q. And when you say you're looking
- at the large counties, can you explain that?
- 18 A. Sure. The ARCOS data that I
- used for the indirect model is the large
- county sample, so these are counties with
- populations of 100,000 or more.
- Q. So it's not limited to Cuyahoga
- 23 and Summit specifically?
- A. That's correct.
- Q. How do the peaks in the MMEs

- 1 compare between the indirect regression and
- the direct regression?
- A. Do you mean in the but-for or
- 4 in the actual?
- 5 Q. Well, in the -- looking just --
- 6 I'll be more clear.
- 7 In looking at Table 5, it looks
- 8 like the highest volume of total MMEs is
- 9 actually in 2011.
- Do you see that?
- 11 A. Yes, I mean, 2010 and 2011 are
- very similar, but it is slightly higher.
- Q. Right. And I'm just trying to
- square that with your direct regression which
- found that there was this era turning point
- in 2010 that resulted in a decline after
- that.
- A. Well, let's have a look at when
- the peak MMEs are as opposed to when I
- estimate the erosion begins to happen.
- So I'm just looking at
- Figure 2. So the absolute peak is in 2011,
- but if you look at 2010, again, it's just a
- bit below 2011. There's sort of a flat spot
- at the top of the curve there, so...

- Q. Okay. So in both regressions,
- the peak is actually in 2011?
- A. Yeah, I think the peak is in
- 4 2011.
- 5 Q. And you agree, based on the
- 6 results of your direct regression, that
- 7 defendants' promotion for opioids had less
- 8 effect after 2010?
- 9 A. According to my model, the
- incremental effect of promotion began
- declining in late 2010, yes.
- 12 Q. Is it the case that the
- majority of the conduct influencing the
- but-for number in your direct model occurred
- 15 before 2010?
- 16 A. I'm just trying to think about
- what's the right way to answer that question.
- You're talking -- we're talking about the
- direct model now?
- Q. Correct. Well, here's my sort
- of question. So you've got conduct over
- time, right?
- 23 A. Yes.
- Q. Starting in '95, right? And
- we've got a growing stock of promotion.

- We've been around all those issues.
- So is it fair to say that given
- the parameters of your direct regression,
- 4 your but-for model is being more heavily
- influenced by the 1995 to 2009 details than
- 6 later details?
- 7 A. It is true based on Model B
- 8 that those earlier detailing will -- I mean,
- 9 it has a longer time to compound effectively.
- What the level of detailing is,
- as you know, it's sort of up and down, so
- it's not a strictly monotonic thing, given
- that there were periods where the level of
- detailing was lower.
- But in general, the model
- suggests that earlier detailing, because it
- has longer time to contribute to sales, for a
- given unit will have a bigger effect on the
- 19 total.
- Q. And you have not run any
- regression model that attempts to show the
- effect of defendants' promotion beginning in
- 23 2009 on prescriptions of opioids after that
- 24 time?
- A. Well, my model incorporates the

1 entire time period. I haven't separately run 2. a model from 2009 forward. I don't think it 3 would be appropriate to run a separate model. 4 One could use my model to run a but-for 5 scenario in the post-estimation sense. 6 Ο. But the issue there, though, is 7 that you still have all these details 8 from '95 to 2009 in your model, which have 9 continuing -- continuing impact after 2009? 10 Well, just to be clear, I'm not 11 sure what your hypothetical is, but if I 12 wanted to know for some reason only what 13 impact detailing from 2009 or any other year 14 was from the present, I'd use the same model, 15 but I would say that actual and but-for 16 promotion are equal up until 2009, so not 17 attributing impact to those earlier details. 18 And then from that point on, 19 then I would reduce the promotional stock by 20 the amount of detailing that happened after 21 that time, so that would be the right way, if 22 for some reason one wanted to look at a 23 shorter time period. 24 And that's not an analysis 25 you've done so far?

- 1 A. It's not, although I mention in
- Table 3 that I could limit my analysis to
- different time periods like that.
- Q. Okay. Table 5 is measuring
- 5 annual estimates based on your indirect
- 6 method on an aggregate basis, correct?
- A. As per my assignment, I'm
- 8 looking at aggregate impact in this model as
- 9 I do in the direct model.
- 10 Q. And it does not measure the
- impact of any specific manufacturer's
- promotion, the indirect model?
- A. Again, I have been asked to
- calculate the aggregate impact, and because
- there are spillover effects across
- manufacturers, I believe here, as I did in
- the direct model, that it is appropriate to
- look not one defendant at a time, but to look
- overall at the underlying issues.
- Q. You don't have any Table 3 or
- related methodology for your indirect
- regression, correct?
- A. I don't have a Table 3 for the
- indirect method because, of course, it's
- indirect, and Table 3, as we have talked

- about at length, generates a different set of
- but-for assumptions by treating promotion
- differently for the subset of defendants.
- 4 Q. And you don't have any
- 5 IQVIA/IPS-type data for the indirect
- 6 regression that you could use to generate an
- allocation the way you have for the direct
- 8 regression?
- A. Again, here, the promotion is
- not directly measured by nature, so that
- doesn't map to defendants in the way it did
- in the direct model. In -- and so I have not
- thought about -- again, because it was not
- part of my assignment, I have not thought
- about allocating this to defendants. I think
- the logical way to do so might be based on
- MMEs.
- 18 Q. But you can't actually allocate
- by MMEs in your indirect model either because
- the ARCOS data is at a molecular level, not
- 21 at an NDC level?
- A. While that is true, I have the
- 23 IQVIA data for the same years that would
- 24 allow me to say within a molecule what share
- is Purdue, et cetera.

- Q. So you'd have to use a
- different dataset mapped onto your indirect
- regression if you were to try to allocate the
- 4 indirect regression across and between
- 5 defendants?
- 6 A. If such allocation were
- 7 necessary for whatever reason, I think that
- 8 would be the best way to do it.
- 9 Q. But as we sit here today, you
- have not done that work and you have no
- opinion as to what that allocation would be
- in your indirect regression?
- 13 A. I have not offered an opinion
- on that matter as you can see in my report.
- Q. Does your indirect regression
- exclude opioid shipments by the
- 17 non-defendants?
- 18 A. No, the indirect method is the
- aggregate market, so it includes
- non-defendants, and hence, the reason to
- include that secular trend.
- Q. So when we look at these excess
- shares, that's not just for defendants'
- promotion, but it's for all promotion?
- 25 A. These excess shares are

- analogous to the excess shares that are in
- Table 2, which is they are the excess share
- of opioid prescribing overall that is
- 4 associated with the misconduct, and again,
- 5 that's the relevant parameter that I need to
- 6 pass on to Professor Cutler.
- 7 Q. And Professor Cutler didn't
- 8 actually use your indirect regression in the
- body of his report; is that correct?
- 10 A. I think in the body of his
- 11 report he uses the direct, and then he
- replicates with the indirect in the -- one of
- his attachments.
- Q. And did you have any
- conversations with Professor Cutler about
- that decision to use the direct in his main
- analysis and address the indirect in an
- 18 attachment?
- 19 A. No.
- Q. Do you know whether Professor
- McGuire uses your indirect regression as an
- input to his analysis?
- A. I do not.
- Q. Did you have any direct
- conversations with Professor McGuire about

- your analysis and how it would translate into
- his analysis?
- A. Yes, at some point.
- Q. Okay. And you understand that
- 5 there's an intermediate step between you and
- 6 Professor McGuire that is Professor Cutler's
- 7 analysis?
- A. Yes. As a general matter, yes,
- 9 I understand how these fit together.
- Q. Okay. Let's turn to Section X
- 11 on page 62.
- So in Section X, the question
- you pose in the heading is Does a Theory of
- Undertreated Pain Explain the Growth in
- Opiate Prescribing.
- Do you see that?
- A. Yes.
- Q. And you say in paragraph 90:
- 19 As an alternative to the defendants'
- 20 marketing as being the explanation for much
- of the rise in opioid prescribing in the
- United States, I understand that some have
- 23 argued an alternative explanation that pain
- was previously undertreated and that the
- growth in opioid shipments is due either to

```
the amount of pain in the United States
```

- increasing over time, or more likely to the
- amount of the opioids used to properly treat
- 4 pain increasing over time.
- 5 Do you see that?
- 6 A. I do.
- 7 Q. And then you say in
- 8 paragraph 91: To test this hypothesis, I
- 9 note there is empirical research on the
- 10 prevalence of uncontrolled pain among cancer
- 11 patients and other patient groups that could
- help us understand how much of the growth in
- opioid shipments could, as a theoretical
- matter, even possibly be attributed to using
- more opioids to treat pain consistent with
- medical evidence.
- Do you see that?
- 18 A. I do.
- 19 Q. Then you've got a footnote that
- cites to a few medical articles by
- Dr. Portenoy, Dr. Cleeland, Dr. Donovan, a
- Marks and Sachar article, and then I won't
- even attempt to say the name of the last
- 24 author.
- Do you see that?

- 1 A. I do.
- Q. And is there any other
- empirical research on uncontrolled pain that
- 4 you reviewed in connection with your report
- 5 that supports the statement in paragraph 91 I
- 6 just read?
- 7 A. Obviously these are the
- 8 articles that I rely on. My point here is
- simply to say that prior to the period of the
- alleged misconduct, people were writing about
- the concerns about uncontrolled pain for
- these particular areas, and I'm simply -- I'm
- not trying to be exhaustive about it; I'm
- just simply showing that there is
- documentation in the academic literature of
- these concerns.
- Q. And academic literature, by
- that you're talking primarily about medical
- ¹⁹ articles, correct?
- A. Well, undertreated pain
- 21 presumably is a medical issue.
- Q. Right. And then in
- paragraph 91 you say, after the sentence I
- read: In this section I use epidemiologic
- data and a simple simulation approach to

- approximate the portion of the increased
- prescribing caused by the allegedly unlawful
- promotion could possibly be associated with
- 4 using opioids to address ostensibly
- 5 undertreated pain.
- A. It seems like I'm missing a
- 7 word there.
- Q. Yeah, I think there's a typo,
- 9 but I read that correctly?
- 10 A. Yes, you did.
- Q. Okay. So in paragraph 91 you
- describe the simple simulation approach,
- which in paragraph 92 you describe as a
- thought experiment.
- Do you see that?
- 16 A. Yes.
- 17 Q. How would the economic
- 18 literature describe the type of analysis
- you're conducting in paragraph 10 of your --
- Section X of your report?
- A. Generally, simulation is the
- word that economists would use to describe
- 23 it.
- O. And is simulation a
- peer-reviewed methodology?

- A. Sure.
- Q. And what papers would I read to
- describe how to conduct a proper simulation
- 4 in economics?
- MR. SOBOL: This one.
- 6 A. Simulations are used in a whole
- 7 variety of settings. In general, the
- 8 cost-effectiveness literature uses simulation
- 9 as a primary methodology.
- 10 BY MR. ROTH:
- 11 Q. Okay. As you sit here now, can
- you think of a specific economics
- peer-reviewed paper that uses a simulation
- approach akin to the approach you take in
- Section X of your expert report?
- A. As I sit here, I couldn't come
- up with a citation for you. My -- my recall
- 18 for article names is not that good, but this
- is -- this is a pretty common approach,
- 20 particularly when it comes to looking at the
- effects of policies, proposed policies.
- Q. Have you published any research
- yourself that utilizes the same type of
- simulation approach that you outlined in
- 25 Section X of your expert report?

- 1 A. I have a recent paper that
- simulates a policy proposal that would, in
- effect, tax companies that raise their
- 4 prescription drug prices above either the CPI
- or some other particular threshold, so that
- 6 uses a simulation approach.
- 7 Q. And if we look at Attachment A,
- which is your CV, can you show me which paper
- 9 you're talking about?
- 10 A. Yeah, let me just see. It was
- just published this year, but I think it
- should be on there. Sorry, that's my other
- documents.
- 14 It's article 119.
- Q. Article 119. Generic
- prescription drug price increases, which
- products will be affected by proposed
- anti-gouging legislation?
- 19 A. That's correct.
- Q. Beyond that article in -- 119
- that you just identified, can you think of
- 22 any other peer-reviewed publications you've
- authored that utilize the same type of
- 24 approach you outline in Section X of your
- 25 report?

- 1 A. There is another one. Let me
- see if -- I just need to figure out what year
- 3 it was.
- 4 Article 34.
- 5 Q. It's helpful that you number
- 6 things, by the way.
- 7 So that's State and Federal
- 8 approaches to health reform: What works for
- 9 the working poor?
- 10 A. That's correct.
- 11 Q. Okay. Anything beyond those
- 12 two?
- 13 A. I think that -- well, actually,
- I mention cost-effective analysis, and the
- article 115 is a cost-effectiveness analysis
- that uses a microsimulation model.
- Q. Cost-effectiveness of Financial
- 18 Incentives for Patients and Physicians to
- 19 Manage Low-Density Lipoprotein Cholesterol
- 20 Levels?
- A. That's correct.
- Q. Okay. So now we have three.
- 23 Any others?
- A. As far as I know, those are the
- relevant articles on my CV. Again, a

- simulation is commonly used as either a whole
- 2 analysis or as part of an analysis.
- 3 Sometimes researchers will take parameters
- 4 that they estimate and then use them to
- 5 simulate a policy change.
- Q. And you've said a couple of
- 7 times now, it's used to simulate a policy
- 8 change.
- 9 Can you explain what you mean
- 10 by that?
- 11 A. Well, in the case of the last
- 12 article that we just talked about that we
- undertook a randomized control trial of
- 14 financial incentives for doctors and patients
- to control cholesterol better, and we took
- what we learned in that randomized control
- trial and said what would happen basically if
- employers were to adopt this widely or if
- health insurance companies were to adopt this
- widely, what would happen to cholesterol
- 21 control and downstream healthcare
- expenditures that would result.
- Q. And to do that, you used a
- simulation similar to the one you used in
- 25 Section X of your report?

- 1 A. Yes, it's based on the same
- premise. We have some epidemiologic data and
- then some information about the relevant
- behaviors, and in this case, the treatment
- 5 patterns for the patients.
- 6 Q. And you call this analysis a
- 7 simulation study or is there some other term
- 8 I should be using?
- 9 A. I call it a simulation, and as
- you can see, I then call it a thought
- 11 experiment.
- 12 Q. Yeah. And it's simple
- simulation and a thought experiment, so I
- wasn't sure which is best. We may use both
- interchangeably, if that's okay.
- A. Sure.
- Q. What is the appropriate
- methodology in economics for conducting a
- simulation study such as the one that you
- have in paragraph 10 of your report?
- A. Well, again, as I mentioned, a
- simulation generally involves some relevant
- 23 population and then some behavioral
- parameters. And, I mean, the context will
- vary.

```
1
                   In other contexts, we're
2.
     looking at patients and their health
     behaviors.
3
                  Simulations are frequently done
4
     around tax policy, so the relevant behaviors
5
     have to do with labor supply, for example.
6
                   And I do call this a simple
7
     simulation here because the only parameters
8
     I'm looking at are treatment patterns.
9
                   If I wanted to find some
           Ο.
10
     peer-reviewed treatise or article that told
11
     me what the appropriate methodology is for a
12
     simple simulation such as the one you conduct
13
     in Section X of your report, where would I
14
     look?
15
                   I am not sure that there would
           Α.
16
     be a single treatise. I think to the extent
17
     that there are methodological frameworks, I
18
     think they're likely context specific.
19
                   So to figure out what the
20
     appropriate generally accepted economic
21
     methodology is for a simulation, I would have
22
     to review a bunch of articles that run
     simulations and determine the best approach
23
24
     myself?
```

I don't know if there's a

Α.

25

```
single methodological paper that would apply
```

- 2 here.
- Q. Okay. So back to
- 4 paragraph 91 --
- 5 A. Okay.
- Q. -- you say at the end of the
- 7 paragraph: In this section, I use
- 8 epidemiological data and a simple simulation
- ⁹ approach.
- We talked about that.
- And then the rest of the
- sentence says: To approximate the portion of
- the increased prescribing caused by the
- 14 allegedly unlawful promotion -- I think you
- meant "that could possibly be associated."
- 16 A. Yes.
- Q. Okay. So when you say
- promotion that could possibly be associated
- with using opioids, as we discussed, you're
- not a medical doctor, right?
- A. That's correct.
- Q. So you're relying on
- plaintiffs' medical experts to tell you what
- those parameters should be?
- A. That's correct, in part, yes.

```
Q. You did not make any
```

- independent assumptions about the type of
- patients that could have benefited medically
- 4 from using opioids?
- MR. SOBOL: Objection.
- A. I -- as you can see and will
- 7 note I talk about, I cite to a number of
- guidelines and articles, and I rely on
- 9 plaintiffs' clinical experts to validate my
- 10 assumptions.
- 11 BY MR. ROTH:
- 12 Q. Right, but since you're not a
- doctor, when you read the guidelines and
- 14 articles, I take it you took direction from
- either a doctor or from counsel about what to
- take out of those articles?
- MR. SOBOL: Objection.
- A. Yes, that's correct.
- 19 BY MR. ROTH:
- Q. Okay. And you don't have any
- 21 medical expertise that you would need to make
- your own independent assumptions about the
- type of patients that could benefit from
- using opioids?
- A. I am not a medical expert.

- Q. I want to look at paragraph 94.
- 2 So towards the bottom of that paragraph, you
- 3 say: Note that because I am not documenting
- 4 the diagnoses and dosing associated with
- 5 actual uses of opioids, I am not able to
- 6 calculate how much of the increased use of
- opioids during the period in which the
- 8 alleged misconduct occurred was in fact for
- 9 clinically appropriate indications, dosages
- and durations.
- Did I read that correctly?
- 12 A. You did.
- 0. And that's similar to what we
- discussed yesterday. None of your analyses
- attempt to parse out whether the excess MMEs
- you identified were for medically appropriate
- uses?
- A. Yes. Again, here I'm trying to
- calculate this maximum, just say let's just
- assume that, in fact, some portion of this
- growth is driven by better treating cancer
- patients, how much could that possibly be?
- But I have not been -- I do not have
- diagnosis codes that would allow me to
- precisely capture that in the data.

```
1 Q. Do you know whether data with
```

- diagnosis codes for Cuyahoga and Summit
- 3 County exists that you could use to do an
- 4 actual analysis?
- 5 A. I don't know about whether data
- 6 are available for Cuyahoga and Summit
- 7 Counties specifically, no.
- Q. And I read the sentence that I
- ⁹ just took from paragraph 94 which you have
- emphasized a few times with italics as a
- limitation on your analysis, correct?
- 12 A. It's a kind of a limitation.
- 13 It's just a really important clarification
- because I would not want someone reading my
- report to interpret the numbers that I've
- simulated to be actually representative of
- how prescriptions were -- you know, according
- to what diagnoses prescriptions were written.
- So it's not really a
- limitation. The purpose of my analysis is to
- do something different, but it should not be
- interpreted as showing how much was actually
- used to address cancer pain.
- Q. Your simulation is a
- 25 hypothetical analysis based on assumptions

- you made from plaintiffs' experts'
- 2 explanation of appropriate uses as opposed to
- a factual assessment of which prescriptions
- were medically necessary?
- 5 A. Yes. I mean, it is based on a
- set of facts, but it does not compute the
- 5 share of prescriptions that were actually
- 8 used for these indications.
- 9 O. So let's look at kind of the
- foundational assumptions you've got in
- paragraph 92.
- 12 A. Okay.
- Q. You say first: I conduct a
- thought experiment that allows me to
- calculate, in scare quotes, upper bound of
- how much of the growth in MMEs could be
- 17 attributable to more intensive pain
- management for patient groups that according
- to plaintiffs' experts could have benefit
- from treatment of -- with opioids.
- Do you see that?
- 22 A. Yes.
- Q. And then you say: All of the
- underlying assumptions in this section have
- been developed in reference to the opinions

- of the plaintiffs' clinical experts,
- including Dr. Schumacher and Dr. Parran.
- Do you see that?
- 4 A. Yes.
- 5 Q. Are there any plaintiffs'
- 6 clinical experts who you rely on that are not
- 7 Dr. Schumacher and Dr. Parran?
- 8 A. Not specifically that I rely
- 9 on, no.
- Q. Okay. I just was confused,
- because you say including, but you only named
- two of them, so I didn't know if there was
- someone else that's missing here.
- 14 A. I understand that there are
- other clinical experts. These are the
- 16 clinical experts that I rely on.
- Q. Did you review or rely on
- Dr. Ballantyne's report?
- 19 A. I did not, no.
- Q. Are you aware that plaintiffs
- have withdrawn Dr. Parran's expert report?
- A. I was not aware of that, no.
- Q. Do you know which of the
- assumptions you made based on Dr. Parran's
- report in this section of yours?

```
1
                   I don't believe any of the
            Α.
2.
     assumptions were solely based on Dr. Parran.
3
                   MR. ROTH: And so the record is
4
            clear for the reporter, we're actually
5
            talking about Parran, P-A-R-R-A-N, who
6
            is actually different than Perri,
7
            P-E-R-R-I. And Schumacher is
8
            S-C-H-U-M-A-C-H-E-R.
9
     BY MR. ROTH:
10
                   Okay. So based on the opinions
            Ο.
11
     of Dr. Schumacher and Dr. Parran, you next
12
     set forth the assumptions you make about what
13
     could possibly have been an appropriate
14
     medical use in paragraph 92?
15
                   MR. SOBOL: Objection.
16
                   Yes, I put forth those three
            Α.
17
     categories of conditions that I understand
18
     have clear benefit from opioids.
19
     BY MR. ROTH:
20
            Ο.
                   Okay. So the first category is
21
     short-term treatment of severe acute pain,
22
     e.g., trauma or postsurgical pain,
23
     end-of-life pain/hospice care and cancer pain
24
     from active malignant disease.
25
            Α.
                   That's right.
```

```
1
            Ο.
                   The second category you list
 2.
     based on Dr. Parran and Dr. Schumacher is
 3
      actually sort of a noncategory, right?
 4
            Α.
                   Yes.
 5
                   Which --
            Ο.
                   Again, I'm sorry to interrupt
 6
            Α.
 7
            Please finish.
     you.
 8
            Q.
                   What you say in (ii) is:
 9
      Chronic opioid therapy is not recommended for
10
     most common chronic pain conditions, defined
11
```

as moderate to severe pain lasting beyond 60

- 13 centralized pain such as fibromyalqia and
- 14 headache pain.

12

- 15 Do you see that?
- 16 Α. I do.
- 17 And we'll talk about this in a Ο.

to 90 days, including low back pain,

- 18 minute, but you actually exclude that from
- 19 your thought experiment?
- 20 That's correct. Α.
- 21 Ο. And then the third category
- 22 which is included is less common chronic pain
- 23 conditions such as pain from advanced
- 24 multiple sclerosis, sickle cell disease, pain
- 25 following spinal cord injury and paraplegia

```
or post-herpetic neuralgia, which comprise a
1
2
     small percentage of chronic pain patients and
3
     for which opioids may be considered a
4
     third-line therapy?
5
                   Do you see that?
6
            Α.
                   I do.
7
                   And actually, really, the only
            Q.
8
     ones you include in your thought experiment
9
     are Romanette (i), which are trauma or
10
     postsurgical pain and cancer pain?
11
            Α.
                   Yes, just -- I was going to
12
     just clarify. In this section in
13
     paragraph 92, I'm summarizing what I
14
     understand the opinions of the clinical
15
     experts have put forward in terms of
16
     appropriate uses broadly, and you're correct
17
     that when I go to implement my analysis, I'm
18
     focusing really on section (i), and I try to
19
     explain why.
20
            Q.
                   Okay. And we'll get there.
21
            Α.
                   Yeah.
22
                   So when you read plaintiffs'
            O.
```

medical experts' reports, what you gleaned

from those reports was that the only

conditions they believed opioids are

23

24

25

```
indicated properly to treat are those
conditions listed in paragraph 92?

MR. SOBOL: Objection.
```

- A. When I read those reports, I
- 5 gleaned everything that I said in that -- in
- that extremely long sentence, which is a
- 7 little more nuanced than I think what you
- gust said.
- 9 BY MR. ROTH:
- Q. Do you know whether plaintiffs'
- 11 medical experts' positions regarding the
- proper indication of opioids today were the
- prevailing medical guidelines for use of
- opioids from 1995 to the present?
- MR. SOBOL: Objection.
- 16 A. I am probably not the person to
- best characterize that, but I have looked at
- some of those guidelines, and I also have
- 19 read the complaint, and I know that
- 20 plaintiffs intend to prove that part of the
- 21 misconduct influenced guidelines that were
- broader than these opinions.
- So I believe by extension it
- must be true that there are quidelines from
- that period that suggest that it is safe to

- use opioids for things like chronic pain.
- 2 BY MR. ROTH:
- Q. And you also understand that
- 4 medical quidelines are not static, correct?
- 5 A. I understand that medical
- 6 quidelines are not static.
- 7 Q. I mean, as a healthcare
- 8 economist, I'm sure you've studied lots of
- 9 drugs where indications and warnings and
- appropriate uses change over time?
- 11 A. Well, more specifically, I know
- in this case that there were updated
- guidelines issued.
- Q. But in your thought experiment,
- you're imposing plaintiffs' experts' 2019
- framework on opioid use from the entire
- period from 1995 to the present?
- 18 A. I think you mistake the purpose
- of my thought experiment. It is not to say
- what would happen if we imposed 2019 beliefs
- by these clinical experts, but rather to say
- in a world in which there was no misconduct,
- to what extent might the appropriate -- sort
- of appropriate efforts to address
- undertreated pain have led to similar

- patterns.
- Q. So if I understand you then,
- your simulation is predicated on plaintiffs
- 4 proving that the existing medical guidelines
- between 1995 and today were wrong as a result
- of defendants' misconduct?
- 7 A. Well, I think that you're
- giving a legal interpretation to my analysis
- 9 that I'm not really in a good position to
- judge.
- What -- the purpose of my
- analysis is to examine whether there might
- have been legitimate clinical drivers of the
- increase in opioids that could have explained
- a similar pattern of growth.
- Again, as I understand it,
- defendants in related matters have said, you
- know, physicians began using opioids more
- heavily in the 1990s because of the
- recognition that pain was undertreated, so
- 21 I'm simply examining that premise.
- Q. But if your premise is to try
- to understand whether there were legitimate
- clinical drivers, why would you not use the
- clinical standards in existence at the time

```
1
     of prescription?
2.
                   MR. SOBOL: Objection, asked
3
            and answered.
                   Those clinical standards are
4
     influenced by the misconduct.
5
6
     BY MR. ROTH:
7
                   So that goes back to my
            Ο.
8
     question.
9
                   An underlying assumption of
10
     Section X, your simulation analysis, is that
11
     plaintiffs can prove that defendants'
12
     misconduct influenced the extant clinical
13
     standards from 1995 until the present?
14
                   MR. SOBOL: Objection, asked
15
            and answered.
16
                   Again, I think that you're --
            Α.
17
     you're putting a sort of liability
18
     interpretation on this that -- that -- this
     is not a but-for analysis. You sound like
19
20
     you're describing it as a but-for analysis.
21
                   It's a thought experiment that
22
     says what if we use opioids to perfectly
23
     treat the patients that we know can be safely
24
     and effectively treated, what would that look
25
     like in comparison to the growth that we
```

- 1 actually saw.
- 2 BY MR. ROTH:
- Q. It's a thought experiment that
- 4 says if the plaintiffs' experts are right
- 5 about what opioids can be used for, then this
- 6 shows how prescriptions compare to what they
- ⁷ say opioids should be used for?
- MR. SOBOL: Objection.
- 9 A. The thought experiment does
- depend on the assumptions about which groups
- could be appropriately treated. That is
- 12 correct.
- 13 BY MR. ROTH:
- Q. Put another way, your thought
- experiment does not measure opioid usage
- against the existing clinical standards in
- place at any point in time?
- MR. SOBOL: Objection.
- 19 A. The thought experiment measures
- the level of opioid use that would have
- occurred -- sort of the highest level of
- opioid use that would have occurred according
- to what I believe plaintiffs' experts intend
- to prove is appropriate.
- It is not based on any

- individual set of guidelines. As I
- mentioned, I am relying on clinical experts'
- opinions in order to identify these groups,
- and so it's not based on a set of guidelines.
- 5 The treatments -- the treatment
- 6 patterns do come from some quidelines that
- 7 I'm sure we will talk about, but again,
- 8 there -- I do -- I do some sensitivity
- 9 analysis, but naturally, the specific
- parameters I choose, including the patient
- groups, do affect the analysis.
- 12 And the reason why I call it a
- thought experiment is this is not intended to
- say this is -- there's only one version of
- this, but instead, to say, well, look, I've
- picked these three important groups, and I've
- assumed that absolutely everyone gets
- treated, and -- and look how little of the
- growth in opioids that explains. If you want
- to add another 50%, it still explains very
- 21 little.
- 22 BY MR. ROTH:
- Q. And what would the basis be for
- adding 50%? Just rough justice?
- A. If you thought for example that

- 1 I was missing a group of patients or that
- 2 my -- that dosing, in fact, could safely be
- 50% higher or that duration could be 50%
- 4 higher.
- 5 Q. I forgot to ask you earlier
- 6 when we were talking about your methodology.
- 7 Have you utilized a simulation approach
- 8 similar to the one in Section X of your
- 9 report in other expert work that you've done?
- 10 And feel free to take a drink.
- 11 A. I'm sorry, now I have the
- 12 reverse problem.
- Q. Let me reask the question
- because the transcript is not clear.
- Have you utilized a simulation
- approach like the one in Section X of your
- report in other expert work that you've done?
- 18 A. In effect, any but-for analysis
- is a simulation. I usually call those
- simulations because they abstract from the
- 21 actual world by changing some set of facts.
- Those are simulations.
- There have also been
- simulations in my expert work, for example,
- in the AWP matter, the damages are basically

- calculated by simulation, assuming that
- instead of whatever markup was actually
- 3 charged, that there would have been only a
- 4 30% markup, for example, on drugs.
- 5 So simulation is very commonly
- 6 used as a damage analysis. Although that's
- 7 not what I'm using it here for.
- Q. Have you used a simulation
- 9 outside of damages analysis in other cases as
- you do in Section X of your report?
- 11 A. I'm not sure whether I have.
- 12 O. So because Section X is based
- on plaintiffs' medical experts' assumptions
- about appropriate use of pain, you do not
- calculate MMEs associated with treatments
- beyond what they include in your analysis?
- MR. SOBOL: Objection.
- A. Oh, I'm sorry. I'm not totally
- sure what you're talking about.
- BY MR. ROTH:
- Q. So we can go through paragraph
- by paragraph and see exactly what types of
- pain -- what types of opioid uses you permit
- based on their opinions.
- 25 A. Yes.

```
1
                   And we'll do that.
            Ο.
                                        But my
 2.
     question is a little different.
 3
                   My question is because you
 4
     limit yourself to what you glean from
 5
     Dr. Schumacher and Dr. Parran are appropriate
 6
     uses of opioids, you do not include other
 7
     uses of opioids that might be appropriate
     under medical guidelines in your simulation
 8
     of MMEs?
10
                   I think it's fair to say that I
            Α.
11
     include the three categories of patients in
12
     my analysis, and by extension, I do not
13
      include others.
14
                   And looking back at
15
     paragraph 92, you took from Dr. Schumacher
16
     and Dr. Parran that chronic opioid therapy is
17
     not recommended for most common chronic pain
18
     indications, correct?
19
            Α.
                   That's what I understood, yes.
20
            Ο.
                   You understand that opioids are
21
     indicated for and labeled for those uses?
22
                   MR. SOBOL: Objection.
23
                   I do know that in some cases
            Α.
     they are labeled for chronic pain.
24
25
                   ///
```

```
BY MR. ROTH:
1
2.
                   So your simulation depends not
           Ο.
3
     only on showing that the medical standards in
     place at the time were wrong, but also that
5
     the FDA should not have approved opioid use
6
     for chronic pain?
7
                   MR. SOBOL: Objection, in part
8
            asked and answered, misstates her
9
           prior testimony.
10
                   Go ahead.
11
                   I would not agree that it
           Α.
12
     depends on that. My analysis conducts this
13
     thought experiment on this group for which it
14
     is clear that -- to clinical experts, as I
15
     understand it, that opioids are appropriately
16
     used.
17
                   For chronic pain patients, I
18
     understand that the clinical opinions that
19
     are being offered by plaintiff experts are of
20
     this mixed form, as I show here, and so I do
21
     not include those patients in my analysis.
22
                   I don't believe that means the
23
     analysis has no utility if, in fact, there's
24
     some subgroup of patients for whom they are
25
     appropriate. But that's, in fact, captured
```

- in these opinions, and we'll go on to talk
- 2 about what the implications are.
- I think my results can be
- 4 viewed in the context of the idea that there
- 5 may be this small group of chronic pain
- 6 patients who benefit from opioids.
- 7 BY MR. ROTH:
- 8 Q. And if you were to include any
- 9 number of chronic pain patients for whom
- opioid use is appropriate in your simulation,
- that would increase the number of potentially
- appropriate MMEs and thus, decrease the gap
- between actual MMEs prescribed and your
- potentially appropriate number?
- MR. SOBOL: Objection.
- 16 A. If you were to add to the
- number of patients and the number of MMEs,
- that would increase the total, yes.
- 19 BY MR. ROTH:
- Q. Have you done any study or
- 21 analysis as to what number of chronic pain
- patients might be an appropriate quantum to
- add to your potentially appropriate group?
- A. So I don't believe that there's
- a single number that I've seen when I look at

- the clinical opinions, as I've summarized
- them here. They're more qualitative.
- And when they refer to
- 4 third-line treatment, I think that is a
- 5 concept that would require understanding what
- 6 percentage of chronic pain patients have
- ⁷ tried and failed to use other therapies.
- Q. So we saw yesterday morning,
- 9 which feels like a long time ago, that
- 10 Excellus Blue Cross Blue Shield in its
- guidelines still approves of the use of
- opioids for pain in some circumstances.
- 13 A. In its formulary, yes, I think
- that's right.
- Q. Okay. And are you aware the
- 16 CDC guidelines also approve opioid use for
- chronic pain in some instances?
- MR. SOBOL: Objection.
- 19 A. I do believe the CDC
- guidelines -- and I'm not sure that I've seen
- the most recent ones, but the CDC guidelines
- do mention chronic pain as a use for opioids.
- BY MR. ROTH:
- Q. And in fact, Dr. Parran himself
- agrees that chronic pain may be clinically

- 1 appropriate for some subset of patients?
 - MR. SOBOL: Objection.
- A. I believe those opinions again
- 4 which are nuanced here summarize that same
- 5 conclusion that you've drawn, that for some
- 6 small group of patients, opioids may be
- ⁷ appropriate.
- 8 BY MR. ROTH:
- 9 Q. Yeah. And I can mark this, but
- I don't know if you just remember. I mean, I
- think he says in his report chronic opioid
- therapy for persons with chronic pain
- conditions is at most indicated in less than
- 10% of patients with chronic pain, and likely
- significantly fewer.
- Do you recall reading that?
- 17 A. That sounds familiar.
- 18 Q. Okay.
- 19 A. Obviously that's -- less than
- 10% is a hard number to plug into a
- 21 simulation.
- Q. It's some nonzero number, and
- he's saying it's somewhere between zero and
- ten without really saying what it is, so I
- would agree with you.

```
1
                   But you recall seeing that he
2.
     didn't say it was totally impermissible?
3
                   MR. SOBOL: Objection.
4
                   He did not -- and I'll slow
5
            And again, I reflect that nuance in my
6
     description here.
7
     BY MR. ROTH:
8
                   You reflect it in your
     description, but you don't reflect any number
9
10
     of chronic pain patients in your simulation.
11
                   That's correct, I explicitly
12
     exclude them.
13
                   (Whereupon, Deposition Exhibit
14
            Rosenthal-24, CDC Guideline for
            Prescribing Opioids for Chronic Pain,
15
16
            United States, 2016, was marked for
17
            identification.)
18
     BY MR. ROTH:
19
                   All right. I'm going to show
20
     you what I'll mark as Exhibit -- no, I don't
21
     want this one. Sorry. She's been so good.
22
                   I know. She has a hard job
            Α.
23
     reading your mind.
24
                   I'm going to mark as Exhibit 24
25
     the CDC guidelines for prescribing opioids
```

- for chronic pain from 2016. And are these
- the quidelines you recall reviewing?
- A. Yes, I have reviewed the 2016
- 4 guidelines.
- 5 Q. And are there more recent
- 6 quidelines than 2016?
- 7 A. I'm not sure. That's -- I was
- g just allowing for the possibility because I
- 9 think there are older quidelines.
- Q. Right. And the older
- guidelines it's fair to say are likely more
- generous in terms of what they suggest is
- appropriate usage for opioids with respect to
- chronic pain than the more recent guidelines?
- MR. SOBOL: Objection.
- A. I don't recall.
- 17 BY MR. ROTH:
- Q. Would you not expect that,
- given the information in medical journals,
- et cetera, about an increased sensitivity
- frankly just to addiction issues and opioids?
- A. I guess it depends on what
- we're comparing it to. If we had guidelines
- from 1990 or 1985, I would expect them to be
- even more cautionary.

```
And have you reviewed the
 1
            0.
 2.
     quidelines from 1980 or 1985?
 3
            Α.
                   I have not.
 4
            Ο.
                   Okay.
                         So you don't know that
 5
     for sure; you're speculating.
 6
            Α.
                   That's correct.
 7
                   MR. SOBOL: You asked her to
 8
            speculate to begin with.
 9
                   MR. ROTH: I know, but now I
10
            need to make clear on the record that
11
            that's what she's doing.
12
     BY MR. ROTH:
13
                   Okay. So these are published
14
     in 2016, which is well into period three of
     your preferred direct regression, correct?
15
16
            Α.
                   That's correct.
17
            Ο.
                   And if you look at the summary
18
     on the first page, it says: This guideline
19
     provides recommendations for primary care
20
     clinicians who are prescribing opioids for
21
     chronic pain outside of active cancer
22
     treatment, palliative care and end-of-life
23
     care.
24
                   Do you see that?
25
            Α.
                   I do.
```

- Q. And do Dr. Parran or
- 2 Dr. Schumacher include any appropriate use of
- opioids for palliative care?
- 4 A. Again, as I summarized their
- 5 statements, they include -- they include
- 6 virtually the same terms, and many of those
- 7 palliative care patients of course are also
- 8 cancer patients.
- 9 Q. And they include cancer
- patients who are not just in hospice in their
- description, correct?
- 12 A. That's correct. Cancer
- patients may be in hospice or not in hospice
- but at the end of life.
- Q. And do you know how the
- journals define end of life?
- A. Well, I think there are
- different ways of looking at end of life, and
- they vary by analysis. I think frequently
- the last 90 days of life are considered end
- of life, but I'm -- I don't know that that's
- 22 a single way of thinking about it.
- Q. And of course, a doctor who's
- an oncologist with a patient may not actually
- know at the time they're prescribing how

- 1 close they are to the end of life to know
- whether they're within that definition,
- 3 right?
- 4 A. I'd be really impressed if they
- 5 did know.
- 6 O. Yeah. I mean, we all have
- 5 stories of relatives or friends who were
- given a month to live and magically lived
- 9 three or four years with cancer.
- MR. SOBOL: Objection.
- 11 BY MR. ROTH:
- Q. Do you know people like that?
- 13 A. I don't, but I'm glad that you
- 14 do.
- The idea of end of life as you
- know in my analysis, I use the actual end of
- life for my simulation, but it may well be
- that some of those people died without
- getting an opioid treatment because their
- doctors were not ready to decide that they
- were at the end of life.
- Q. And there may also be people
- who the doctor thinks is at the end of life
- that they give an opioid to who actually live
- longer than the 90-day window in the

```
definition?
```

- 2 A. Yes. I think that is less
- often the case, given doctors' general
- 4 reluctance. It's sort of a well-known fact
- 5 in health policy that doctors are reluctant
- to acknowledge that the end of life has
- ⁷ arrived.
- 8 Q. But doctors may decide to treat
- 9 a cancer patient with an opioid even if they
- don't believe that patient is near the end of
- life to treat their pain from the malignancy.
- 12 A. That may well be true, but
- again, in my simulation, I'm looking at
- patients who are actually at the end of life.
- Q. Okay. And by looking at only
- patients who are actually at the end of life,
- you're undercounting cancer patients who may
- be appropriately treated with an opioid to
- address malignant cancer pain but are not yet
- at the end of life?
- A. I will not be including those
- patients who are not at the end of life, and
- we can go back to paragraph 92 to see that,
- like chronic pain, my understanding of
- clinical experts' opinions about patients who

- are not at the end of life who are
- 2 experiencing cancer pain is -- that the same
- 3 challenges pertain to opioid prescribing in
- 4 terms of tradeoffs between possible addiction
- ⁵ risks.
- 6 Q. So looking back at the summary,
- ⁷ it then says, after the first sentence: The
- guideline addresses, 1, when to initiate or
- 9 continue opioids for chronic pain; 2, opioid
- selection, dosage, duration, follow-up and
- discontinuation; and 3, assessing risk and
- addressing harms of opioid use.
- Do you see that?
- 14 A. I do.
- Q. And these guidelines were
- developed by the CDC, correct?
- 17 A. Yes.
- 18 O. The Centers for Disease
- 19 Control.
- A. That's right.
- Q. And they were developed in
- 20 2016, well into sensitivity around opioid
- use, addiction and mortality?
- MR. SOBOL: Objection, scope.
- A. It is certainly true at that

- time period that the opioid epidemic had been
- ² recognized.
- 3 BY MR. ROTH:
- 4 Q. And then if you look at the
- introduction in the background section, the
- first sentence says: Opioids are commonly
- 7 prescribed for pain.
- 8 Do you see that?
- 9 A. Yes.
- Q. An estimated 20% of patients
- 11 presenting to physician offices with
- noncancer pain symptoms or pain-related
- diagnoses, including acute and chronic pain,
- 14 received an opioid prescription.
- Do you see that?
- A. Yes. And I'm certainly
- familiar with that fact.
- Q. So if 20% of patients are
- receiving opioids for pain, that's a fairly
- large population of people. Would you agree
- with that?
- MR. SOBOL: Objection.
- A. Well, yes. I mean, you're
- familiar with the litigation that we're all
- involved in, and that is the subject of this

- 1 litigation.
- So even in 2016, as prescribing
- rates have begun to fall, they are well above
- 4 the levels that are -- were observed 20 years
- 5 ago. So this is precisely the issue that
- 6 we're talking about is that opioids are
- overused, according to clinical experts.
- 8 BY MR. ROTH:
- 9 Q. Well, they're well above the
- level of 20 years ago, but there have been a
- 11 number of new drugs and generics that have
- entered the market over the last 20 years,
- 13 correct?
- MR. SOBOL: Objection.
- A. Well, the fact that there are
- new drugs and generics does not mean that
- increased use is appropriate.
- 18 BY MR. ROTH:
- Q. And the mere fact that use has
- increased over what it was 20 years ago in
- 21 and of itself does not mean that all of that
- increase is inappropriate either.
- MR. SOBOL: Objection, scope.
- A. In my analysis, as I noted
- earlier, I'm not parsing the actual uses.

- 1 And because that is not possible to do in the
- data, I instead come from the other
- direction, which is to say, okay, let's look
- 4 at those uses which are not contested. How
- 5 much of the growth could they possibly
- 6 explain.
- So if the allegations are true,
- 8 my direct analysis shows a large percentage
- of prescriptions were caused by the unlawful
- 10 conduct, and then from this other direction,
- it appears that the uses that the clinical
- experts in this matter for plaintiffs
- consider to be the most appropriate uses only
- account for a very small percentage of the
- 15 total.
- So the statements that you've
- made are sweeping statements. Mine are much
- more precise.
- 19 BY MR. ROTH:
- Q. Put another way, if Dr. Parran
- and Dr. Schumacher and plaintiffs' opinions
- about the appropriate use of opioids were the
- prevailing medical standard, there would be
- an extremely small percentage of patients who
- currently receive opioids in our world that

```
1
     would receive them?
2.
                   MR. SOBOL: Objection, scope.
3
           Α.
                   Of course it depends on what
4
     you mean, if there's a certain path
5
     dependence, as I'm sure you're well aware.
6
     If we come in today and try to unwind
7
     prescribing, there are patients who are
8
     already addicted to opioids.
9
                   But if a world happened in
10
     which only the uses described by the clinical
11
     experts, plaintiffs' clinical experts were
12
     those that for which opioids were used,
13
     you're right, that we would see a dramatic
14
     reduction in opioid use. That is the entire
15
     purpose and conclusion of my analysis.
16
     BY MR. ROTH:
17
            Q.
                   And if you look at paragraph 1
18
     under the background section in this
19
     article -- in the quidelines, the last
20
     sentence says: Rates of opioid prescribing
21
     vary greatly across states in ways that
22
     cannot be explained by the lack -- sorry, let
23
     me start over.
24
                   The CDC quidelines say:
```

of opioid prescribing vary greatly across

- 1 states in ways that cannot be explained by
- the underlying health status of the
- population, highlighting the lack of
- 4 consensus among clinicians on how to use
- 5 opioid pain medication.
- Do you see that?
- 7 A. I do.
- Q. So if marketing is national,
- 9 and all physicians are equally affected by
- marketing, what explains the geographic
- variation in prescribing the CDC is
- 12 highlighting?
- MR. SOBOL: Objection, scope.
- 14 A. Well, as we talked about
- before, and as you can see in the indirect
- analysis, there are county-level factors that
- explain variation in shipments.
- 18 BY MR. ROTH:
- 19 Q. My question was a little
- different.
- This article is talking about
- variation in prescribing, and what I'm trying
- to understand is if marketing is national and
- all doctors are affected, how could it be
- that there is variation in prescribing on a

geographic basis? 1 2. MR. SOBOL: Objection, scope. 3 Α. There -- prescribing and 4 shipments are not different things. They're 5 the same thing. The shipments result from 6 prescriptions. And there are different 7 baselines in different geographic areas, 8 different baselines in terms of the level of use, in terms of all of those socioeconomic 10 and demographic factors. 11 THE WITNESS: I hope you can't 12 hear that on the tape. 13 So that variation exists, and Α. 14 then if a national promotional campaign will have different effects based on the 15 16 underlying area characteristics. 17 BY MR. ROTH: 18 And the CDC highlights that 19 there's a lack of consensus among clinicians 20 on how to use opioid medication. 21 Do you see that? 22 I do see that. Α. 23 Ο. And again, that means that promotion alone is not driving some consensus 24

view as to the efficacy and safety of

```
1
     opioids?
2.
                   MR. SOBOL: Objection, scope.
3
            Α.
                   Well, I'm not sure how you
4
     derive anything from this about promotion.
5
     The fact that there's a lack of consensus
6
     among clinicians does not mean that promotion
7
     hasn't driven this increase in the aggregate.
8
     There may well be variation among clinicians
9
     in the extent to which they've responded to
10
     that promotion, but again, in the aggregate,
11
     that's really what my analysis is about, is
12
     what is the total.
13
                   There may be variation across
14
     areas and across physicians, and still the
15
     question is sort of what has happened to the
16
     overall growth over this time period.
17
            Q.
                   How much aggregation do you
18
     need to do to show that promotion has an
19
     overall growth effect?
20
            Α.
                   I'm not sure I understand your
21
     question.
22
            Ο.
                   Well, we seem to be agreeing
23
     that at a physician level there could be
24
     variation in the effect of promotion, right?
25
            Α.
                   There can be variation at a
```

1 physician level. That doesn't mean -- my 2. point was that physicians may start in 3 different places, they may be -- they may 4 have a bigger effect because they have more 5 patients of a particular type, but -- but 6 still, there's a total effect. 7 And again, in this matter as I 8 understand it, the court needs to know what the whole effect is, and the fact that it may 10 be smaller for one physician and larger for 11 another is -- does not seem relevant as I 12 understand it to the task of proving impact. 13 Understood. But even when Ο. 14 aggregated up to a geographic level, the CDC 15 is highlighting a lack of consensus among 16 clinicians, and I agree that marketing may 17 not affect all doctors equally, but your 18 model seems to suggest that everyone is 19 equally affected by marketing. 20 MR. SOBOL: Objection, asked 21 and answered. 22 You misunderstand the nature of Α. 23 an aggregate model. Again, I calculate an average effect. I do not assume that there's 24 25 no variation in that average.

```
1
     BY MR. ROTH:
2.
                   Right. So that gets back to
           Ο.
3
     the question I asked three questions ago.
                   How much do you need to
4
5
     average? How far up the chain do you need to
6
          It's not at the doctor level, it's not
     qo?
7
     at the geographic level. Where do you start
8
     seeing the aggregative effects overcome
9
     variation in the effect of promotion?
10
                   I'm sorry, I don't mean to
11
     laugh, but that is just a very strange idea.
12
                   So anything you average over
13
     has variation. So at any level the average
14
     captures variation. And again, what I'm
15
     interested in here is the aggregate effect,
16
     and so I have looked at that effect. If one
17
     were interested in ascertaining something
18
     about variability, then you would
19
     disaggregate the data.
20
                   But the -- every average
     contains some kind of variation unless it's
21
22
     not a very interesting average of things that
23
     are exactly alike.
24
                   Let's look at page 3, the top
25
     paragraph on the left side says:
```

- 1 Professional organizations, states and
- federal agencies, e.g., the American Pain
- 3 Society/American Academy of Pain Medicine,
- 4 the Washington Agency Medical Directors Group
- 5 and the U.S. Department of Veteran
- 6 Affairs/Department of Defense have developed
- ⁷ guidelines for opioid prescribing.
- 8 Do you see that?
- 9 A. I do.
- Q. And why do you think the
- Department of Veteran Affairs and Department
- of Defense has their own guidelines for
- opioid prescribing?
- MR. SOBOL: Objection, scope.
- 15 A. Because they provide medical
- care or reimburse medical care for active
- duty -- what is the general word -- military,
- active duty military as well as veterans.
- 19 BY MR. ROTH:
- Q. And then it says: Existing
- guidelines share some common elements,
- including dosing thresholds, cautious
- titration and risk mitigation strategies such
- 24 as using risk assessment tools, treatment
- agreements and urine drug testing. However,

```
there is considerable variability in the
```

- specific recommendations, e.g., range of
- dosing thresholds of 90 morphine milligram
- 4 equivalents a day to 200 morphine milligram
- equivalents a day, audience, e.g., primary
- 6 care physicians versus specialists, use of
- ⁷ evidence, e.g., systematic review, grading of
- 8 evidence and recommendations and role of
- 9 expert opinion, and rigor of methods for
- addressing conflict of interest.
- Do you see that?
- 12 A. I do.
- Q. And then it says: Most
- quidelines, especially those that are not
- based on evidence from scientific studies
- published in 2010 or later, also do not
- 17 reflect the most recent scientific evidence
- about risks related to opioid dosage.
- So not only is there regional
- variation, but actually in the medical
- community, there's variation in prescribing
- standards for opioids?
- MR. SOBOL: Objection, scope.
- 24 BY MR. ROTH:
- Q. Do you agree that's what the

```
1 CDC is saying?
```

- MR. SOBOL: Objection, scope.
- A. I think what the CDC is saying
- 4 is that both across professional
- organizations -- I think it's a little
- 6 broader than the medical community, since
- 7 we're talking about agencies, that guidelines
- 8 vary.
- 9 BY MR. ROTH:
- Q. And I assume, based on your
- 11 testimony throughout the last two days and
- this sort of contagion effect that Dr. Perri
- coined, your view would be that those medical
- 14 associations are influenced by the effect of
- manufacturers' promotion as well?
- A. I believe that plaintiffs
- specifically point to those influences in the
- complaint, and so, of course, that is --
- between that and Dr. Perri's report is where
- I get my information. I have not made an
- individual assessment of this.
- Q. Again I ask, if promotion is
- this unifying thing that influences all
- physicians equally, why is there a
- variability in the guidelines that

```
1
     professional organizations come out with for
2.
     the prescription and use of opioids?
3
                   MR. SOBOL: Objection,
4
            mischaracterizes prior testimony.
5
            Α.
                   As I noted earlier, promotion
6
     will have effects that are different for
7
     different physicians, no doubt different
     professional organizations.
8
9
                   Because it has the same
10
     direction of effect doesn't mean they all
11
     start in the same place or end in the same
12
     place, and so quidelines vary across a number
13
     of seemingly well-accepted clinical areas.
14
     BY MR. ROTH:
                   And the effect that promotion
15
            0.
16
     has, if any, on those guidelines will also
17
     vary?
                   The effect of promotion on
18
            Α.
19
     those quidelines may also vary.
20
                   And neither your direct nor
            Q.
21
     indirect regression models do anything to
22
     measure the effect of medical quidelines on
23
     the prescription and use of opioids?
24
                   MR. SOBOL: Objection, asked
25
            and answered, mischaracterizes prior
```

- 1 testimony.
- 2 A. The direct model, Model C,
- includes events for guideline dissemination,
- 4 and -- and the guidelines are not included in
- 5 the indirect model.
- 6 BY MR. ROTH:
- 7 Q. In Model C you've got the five
- events -- I don't remember all of them from
- 9 memory. I probably will soon. I think one
- was the joint consensus statement, which was
- a guideline; is that right?
- 12 A. Yes, that's correct.
- Q. Were any of the others
- 14 quidelines?
- 15 A. The JCAHO standards are similar
- to guidelines in they set expectations for
- hospitals.
- Q. Okay. And beyond those two, I
- don't think the other three events were
- ²⁰ guideline related.
- 21 A. Federation of State Medical
- Boards, those, I believe, are focused really
- on liability issues.
- Q. Did you consider using, for
- example, the CDC guidelines or other

- guidelines to test how your model would
- 2 respond in Model C?
- MR. SOBOL: Objection.
- 4 A. The CDC quidelines come out in
- 5 2016, which is at the tail end of my data,
- 6 and as we talked about before, it was
- 7 apparent to me when I included five events
- 8 that simply adding more effects was not going
- ⁹ to improve the performance of the model.
- 10 BY MR. ROTH:
- 11 Q. It wouldn't improve the
- performance of the model, but it might show
- that the performance of the model didn't
- stand up once you added multiple events?
- MR. SOBOL: Objection, asked
- and answered.
- A. Well, the fact that a model
- with more events did not look good doesn't
- mean the model that I chose with no events
- was unreliable.
- BY MR. ROTH:
- Q. If you look at page 17 of the
- 23 CDC quidelines --
- A. Incidentally by the way, I
- didn't try that model, so I don't know what

```
it looks like.
 1
 2.
            Ο.
                   Good clarification.
 3
                   So page 17 is the start of a
 4
     long discussion of 12 bolded points that
 5
     clinicians should consider when prescribing
     opioids for chronic pain.
 6
 7
                   Do you see that?
                   I see -- let's see.
 8
            Α.
 9
            O.
                   There are headings in
10
     between --
11
            Α.
                   Yes.
12
                    -- so it's hard to track,
            Q.
13
     but --
14
            Α.
                   I see 12, yes.
15
                   Okay. And again, this is not
            Ο.
     consistent with the view that no patients
16
17
     should ever receive opioid for chronic pain;
18
     it just highlights thing clinicians should
19
     consider before prescribing opioids for
20
     chronic pain?
21
                   MR. SOBOL: Objection, scope.
22
                   I don't believe anywhere in my
            Α.
23
     report I summarize a clinician's opinion that
24
     no patients should receive opioids for
25
     chronic pain.
```

```
BY MR. ROTH:
 1
 2.
                   I don't want to go through all
            Ο.
 3
     12, but I do want to ask about a couple.
 4
            Α.
                   Okay.
                   So if you look at page 21.
 5
            Ο.
 6
            Α.
                   Sure.
 7
                   Number 4 in the section Opioid
            Ο.
 8
     Selection, Dosage, Duration, Follow-Up and
     Discontinuation.
 9
                   Do you see that?
10
11
            Α.
                   I do.
12
                   It says: When starting opioid
            Q.
13
     therapy for chronic pain, clinicians should
14
     prescribe immediate-release opioids instead
     of extended-release/long-acting, ER/LA,
15
16
     opioids, recommendation category A, evidence
17
     type, 4.
18
                   Do you see that?
19
            Α.
                   I do.
20
                   So the CDC is making some
            Ο.
21
     distinction between immediate-release and
22
     extended-release long-acting opioids.
23
                   Do you agree with that?
                   Yes, this recommendation
24
            Α.
25
     specifically applies to immediate-release
```

```
opioids, yes.

Q. And your models don't

distinguish between immediate-release or
```

- 4 extended-release opioids or any other
- 5 distinguishing characteristics of opioids
- other than calibrating them based on MMEs?
- 7 MR. SOBOL: Objection.
- A. In order to accurately capture
- 9 the impact of the alleged misconduct, I
- include all forms of opioids, including
- short- and long-acting.
- My model is intended to capture
- any spillover effects, and to the extent that
- marketing of one product affects use of
- another, it appropriately captures those
- spillover effects.
- To the extent that marketing
- does not have spillover effects, they won't
- be detected inappropriately.
- BY MR. ROTH:
- Q. Number 5 says -- it's on
- page 22 -- when opioids are started,
- clinicians should prescribe the lowest
- effective dosage. Clinicians should use
- caution when prescribing opioids of any

- dosage, should carefully reassess evidence of
- 2 individual benefits and risks when
- 3 considering increasing dosage to greater than
- or equal to 50 MME per day, and should avoid
- 5 increasing dosage to greater than or equal to
- 6 90 MME per day, or carefully justify a
- decision to titrate dosage to greater than or
- 8 equal to 90 MME per day.
- 9 Do you see that?
- 10 A. I do.
- 11 Q. So the CDC seems to be making a
- distinction in terms of potency with respect
- to the clinical guidelines.
- MR. SOBOL: Objection.
- A. Okay.
- MR. SOBOL: Scope.
- A. So they're talking about
- effective dosing.
- 19 BY MR. ROTH:
- Q. And again, that's not something
- you control for in your regression models?
- A. That doesn't make any sense as
- 23 something to control for. Again, I
- 24 appropriately used the number of MMEs as the
- dependent variable, so that is recognizing

- that the number of MMEs is what is clinically
- 2 relevant when it comes to ultimately the
- 3 harms that Professor Cutler looks at.
- 4 And so I do, in fact, capture
- 5 MMEs in my model.
- 6 Q. Okay. So we had an extended
- 7 conversation yesterday about the depreciation
- 8 factor, and you said it was justified because
- 9 opioids are addictive and patients need to
- titrate up.
- Do you remember that?
- A. Yes.
- 13 Q. How does that assumption hold
- in light of the CDC's clinical guidelines
- suggesting that physicians should maintain
- patients on lower doses?
- MR. SOBOL: Objection, form.
- You can answer.
- A. Are you suggesting that because
- the 2016 guidelines warn physicians on not
- increasing doses that none of that happened
- during the period of my analysis, 1995 to
- 23 2018?
- 24 BY MR. ROTH:
- Q. Well, I'm asking the questions,

```
1
     but I'm just suggesting that you didn't
2.
     account for it in your analysis, including
3
     after 2016 when these guidelines were
4
     published.
5
                   MR. SOBOL: Objection.
6
                   You can answer.
7
                   I would respectfully disagree
           Α.
8
     with that characterization. My analysis
9
     incorporates exactly that, and yesterday we
10
     had a brief conversation about a chart that
11
     shows the increasing MMEs per prescription
12
     that demonstrate that doctors were clearly
13
     not following this guideline.
14
                   This is precisely the concern
15
     with the opioid epidemic is that dosing has
16
     continued to ramp up, and, you know, whether
17
     or not this quideline has influenced
18
     physicians to date, there's certainly plenty
19
     of evidence that there were increased dosing
20
     patterns over time for patients who were on
21
     opioids.
22
                   MR. ROTH: Okay. Why don't we
23
            stop for a minute. I don't know if
24
            lunch is here, but this would not be a
25
           bad time to break since it's around
```

```
1
            noon.
2.
                   THE WITNESS: Sure, that's
3
            great.
4
                   THE VIDEOGRAPHER: The time is
5
            11:54 a.m. We're now off the record.
6
                   (Recess taken, 11:54 a.m. to
7
            12:30 p.m.)
8
                   THE VIDEOGRAPHER:
                                       The time is
9
            12:30 p.m. We're back on the record.
10
     BY MR. ROTH:
                   All right. So I'd like to go
11
            Ο.
12
     kind of component by component through your
13
     simulation on appropriate use, if that's
14
     okay.
15
           Α.
                   Okay. Great. I'll just get to
16
     the right section.
17
            Q.
                   Paragraph 95 is the start of
18
     the cancer pain section.
19
                   Are you there?
20
            Α.
                   Yes.
                   So you say: The first group of
21
            Ο.
22
     patients with potentially undertreated pain
23
     includes cancer patients at the end of life/
24
     in hospice. I use epidemiologic data on
25
     cancer deaths in each year to identify the
```

- size of this population.
- 2 And that's consistent with what
- you said earlier, you just looked at
- 4 end-of-life cancer patients, correct?
- 5 A. That's correct.
- 6 Q. Why just limit to end-of-life
- 7 cancer patients as opposed to patients with
- 8 other malignancy associated with cancer?
- 9 A. Sure. As I understand clinical
- experts' opinions and just some of the basic
- risks of opioids, that, of course, people at
- the end of life, the -- any concern about
- addiction is attenuated because of the fact
- that their timeline is short.
- And so those patients are
- distinct from patients who may have continued
- use and continued life beyond -- beyond the
- point of malignant cancer pain.
- 19 Q. So -- but in paragraph 92 when
- you summarize Dr. Schumacher and Dr. Parran,
- you separately refer to end-of-life pain,
- hospice care and cancer pain from active
- malignant disease.
- Do you see that?
- A. Yes, that's correct. So again,

- in footnote 121, I explain a bit there. I
- say I do not attempt to separately identify
- 3 these patients for lack of complete data and
- 4 because I understand there's more clinical
- 5 nuance, so again, that doctors will need to
- trade off addiction risks in those patients
- 7 as I understand the clinical opinions.
- Q. Okay. So your thought analysis
- just includes end-of-life cancer patients,
- 10 not other cancer parents with malignant
- disease for the reasons you say in
- 12 footnote 121?
- 13 A. Yes, that's correct.
- Q. Why do you not include other
- patients in hospice beyond cancer patients?
- 16 A. Yes, again, a two-part -- and
- 17 I'm trying to see exactly what I say in
- footnote 121. But many patients in hospice
- are in fact cancer patients. Cancer patients
- are really the group of patients for whom
- hospice was originally designed, and while it
- has spread to other reasons that people are
- facing the end of life, cancer patients are,
- particularly in the early years, I believe,
- based on the -- my general knowledge of

- hospice, the majority of those patients.
- Q. Have you studied a breakdown of
- the demographics of hospice by diagnosis to
- 4 know that that's true?
- 5 A. I know just from my knowledge
- of the area that cancer has been the
- 7 condition around which hospice -- both
- 8 hospice and really palliative care have been
- 9 focused in the beginning, and it's a general
- health policy debate, the need to expand
- hospice and palliative care to other groups,
- so I understand that cancer is a dominant
- condition for those groups.
- Q. You are aware that patients
- with other medical diagnoses than cancer may
- wind up in hospice?
- 17 A. Yes, I'm aware of that.
- Q. Congestive heart failure
- patients could be in hospice, correct?
- A. Yes.
- Q. Or ALS patients, correct?
- 22 A. Yes.
- Q. And we can play this game --
- A. I am aware of that.
- Q. -- with many conditions that

- are unfortunately terminal, but no matter,
- you only include the cancer hospice patients
- in your thought analysis.
- 4 A. Well, I include cancer patients
- 5 at the end of life.
- Q. Right. You make no attempt to
- 7 capture other noncancer-diagnosed hospice
- 8 patients at the end of life?
- 9 A. I do not. And again, as I note
- in footnote 121, I believe, my sensitivity
- analysis will likely capture those groups.
- Q. Well, in footnote 121, you're
- actually just talking about -- yeah, okay. I
- see, patients dying from other conditions.
- Okay.
- And then in order to calculate
- the amount of -- well, let me backtrack
- because I can't let this go.
- 19 So when you say your
- sensitivity analysis, that's truly just
- modeling a 50% increase in your parameters?
- MR. SOBOL: Objection.
- A. The sensitivity analysis is
- modeling a 50% increase, so that could
- pertain to a 50% increase in the populations

- 1 treated.
- 2 BY MR. ROTH:
- Q. And where did you come up with
- 4 50%?
- 5 A. In simulation analysis, people
- frequently use estimates to get at possible
- measurement error, which are inherently
- 8 speculative. So this was to me a very
- 9 generous speculation about how big the error
- 10 could be.
- 11 Q. It's a statistical choice, it's
- not a choice based on any analysis of medical
- data?
- 14 A. It is a modeling choice, yes.
- Q. Okay. And then in paragraph 96
- you say: For my simulation I take a
- conservative approach and assume that 100% of
- cancer patients at the end of life need and
- want a high dose of oral extended-release
- opioids.
- Do you see that?
- A. I do, except you corrected my
- order.
- Q. I transposed -- I think your
- order is fine, I just transposed it for some

```
1
     reason.
 2.
                   Then you say: This assumption
 3
     is extremely conservative in light of
 4
     plaintiffs' clinical expert, Dr. Parran's,
 5
     opinion.
 6
                   Do you see that?
 7
            Α.
                   Yes.
 8
                   And Parran's been withdrawn.
            Ο.
 9
     Do you have any other basis for saying that
10
     it's extremely conservative to assume that
11
     all cancer patients at the end of life need
12
     and want a high dose of opioids?
13
                   MR. SOBOL: Objection.
```

- 14 Well, I think it's -- I'm not a Α. 15 clinician, so I -- I think it's unreasonable 16 to assume that a hundred percent of patients 17 want anything, particularly given the side 18 effects of opioids unrelated to addiction, 19 increased risk of death from respiratory
- 20 issues, et cetera.
- So I would say that a hundred 21

percent must be conservative.

23 BY MR. ROTH:

- 24 And then you say: For dosing,
- 25 my baseline assumption is 80 MMEs per day,

- which is consistent with average dosing in
- 2 cancer patients reported in public studies.
- Do you see that?
- 4 A. I do.
- 5 Q. Then you cite the Haider
- 6 Journal of Oncology article?
- A. Yes, that's correct.
- Q. Are there any other published
- 9 studies you're relying on, or is that the one
- you're relying on?
- 11 A. That's the one I rely on, and
- as noted, those choices were reviewed by
- Dr. Schumacher and Parran.
- Q. And I assume, since you're not
- a doctor, the Haider study was something that
- either Dr. Schumacher, Dr. Parran or counsel
- directed you to?
- A. I believe that I identified
- that article.
- Q. Okay. Spending time on PubMed?
- A. I spend a lot of time on
- PubMed. As you know, the clinical literature
- 23 and the health services research literature
- are quite overlapping. If you've looked at
- my CVs, I have -- have I published in an

- oncology journal? I believe I have.
- Q. So we talked about dosing,
- which we'll talk about again in a minute, but
- 4 then you say for duration, that you use the
- 5 average duration of treatment reported for
- 6 cancer palliative care as your baseline,
- 7 which is roughly 64 days.
- A. That's correct.
- 9 Q. And where -- that is based on
- the Carlson study, it looks like?
- 11 A. Yes, it is.
- Q. Okay. And so in your thought
- experiment, if a cancer patient lives a year
- in excruciating pain, there would be no
- medically appropriate use for opioids for
- that patient?
- MR. SOBOL: Objection.
- A. Well, I'm not offering a
- clinical opinion here. I'm conducting an
- 20 economic simulation based on clinical
- 21 parameters that are identified from the
- literature and plaintiffs' clinical experts.
- So I'm not saying one way or
- another whether someone who lives beyond
- those expectations should or shouldn't get an

```
1
     opioid.
2.
     BY MR. ROTH:
3
           Ο.
                   So you're not making a medical
4
     judgment or a qualitative judgment, but
5
     you're still deciding not to include that
6
     patient in your potentially acceptable
7
     population?
8
                   MR. SOBOL: Objection.
                                            Excuse
9
           me. Objection.
10
                   The simulation again, it
           Α.
11
     assumes that every single patient gets some
12
     opioid, and then assigns a typical payment
13
     based on the sources that I've cited.
14
     length of stay there is an average, so
15
     unfortunately, we know that many patients do
16
     not actually know that they're dying more
17
     than a week or two before they die. As we
18
     talked about before, physicians tend to be
19
     reluctant to address those issues.
20
                   So I would imagine there are
21
     many patients who in fact would get this kind
22
     of opioid treatment for much less than the
23
     64 days, and there may well be some that get
24
     it for more. But if the duration on average
25
```

captures that, my simulation will reflect it.

```
1
     BY MR. ROTH:
 2.
                   It's like with your other
            Ο.
 3
     model, it's an average. So there are going
 4
     to be people above and below the average with
 5
     respect to treatment time?
 6
            Α.
                   And nonetheless, the aggregate
 7
     will still be representative.
 8
                   You can average anything,
            Ο.
 9
     right?
10
                   MR. SOBOL: Objection.
11
                   Well, if I'm trying to
            Α.
12
     calculate a total, which is what I'm trying
13
     to do here, then the average is a sufficient
14
     statistic for that total, and so that's --
     that's why I use it here.
15
16
     BY MR. ROTH:
17
                   Just so I understand it,
            Q.
18
     though, obviously there's sample size issues
19
     when you average something, correct?
20
            Α.
                   Sample size issues pertain to
21
     standard deviations, not to the mean, and
22
     here again, I'm using this simulation
23
     approach to show an average and not to
24
     characterize the variance around that.
```

(Whereupon, Deposition Exhibit

```
1
            Rosenthal-25, 2017 Haider et al
 2.
            Publication, was marked for
 3
            identification.)
 4
     BY MR. ROTH:
 5
                   I'm going to mark as Exhibit 25
            Ο.
 6
     an article entitled Opioid Prescription
 7
     Trends Among Patients with Cancer Referred to
 8
     Outpatient Palliative Care Over a 6-Year
     Period.
 9
10
                   Is this the Haider study that
11
     you cite in footnote 124 of your report?
12
            Α.
                   It is.
13
                   And that's the study you relied
            Ο.
14
     on to come up with the baseline assumption of
15
     80 MMEs per day?
16
                   That's right.
            Α.
17
            Ο.
                   Okay. So if you look on the
18
     cover page, under Material and Methods, the
19
     last sentence says: Data collected included
20
     demographics, cancer type and stage, symptom
21
     assessment, performance status, opioid type
22
     and opioid dose defined as the morphine
23
     equivalent daily dose.
24
                   Do you see that?
25
            Α.
                   I do.
```

- Q. And then in Results, it says:
- In 2010, median morphine equivalent daily
- dose before referral was 78 milligrams per
- day. However, by 2015, the morphine
- 5 equivalent daily dose had progressively
- decreased to 40 milligrams per day.
- 7 A. I see that.
- Q. And this study looks at the
- 9 number of MMEs prescribed to 750 patients who
- were seen as new consultations at MD Anderson
- 11 Cancer Center between January 1st and
- 12 April 30th each year from 2010 and 2015?
- 13 A. That's correct.
- Q. And this is the only article
- you rely on for your conclusion that the
- appropriate treatment is 80 morphine
- milligram equivalents per day?
- A. Again, yes, this is the article
- where I found that dosing and referred it to
- the clinical experts for their input.
- Q. And this dosing, again, is for
- patients who were at the cancer center's
- outpatient palliative care clinic, correct?
- A. That's correct.
- Q. It's not at a hospice facility?

- A. It was not.
- Q. So you don't have any articles
- that you relied on to evaluate the
- 4 appropriate dosage in MMEs given to
- 5 end-of-life cancer patients at hospice?
- A. This high dose estimate was the
- 7 estimate that I found that was closest to
- 8 what I was looking for. I think some of
- 9 these patients may be at the end of life and
- some are not.
- Q. And if patients are not yet at
- the end of life, would you expect their
- opioid dosing to be higher or lower than
- patients in hospice?
- 15 A. It may be, again, that this 80
- number is lower. I don't know for sure.
- 17 Again, why I do the sensitivity analysis by
- saying what if it were 50% higher, so not 80,
- ¹⁹ but 120.
- Q. And again, you're not a medical
- doctor, so beyond the Haider article, do you
- have any basis to say what an appropriate
- opioid dosage is in MMEs for a hospice
- patient?
- MR. SOBOL: Objection.

- 1 A. Again, I refer these
- 2 assumptions to the clinical experts for them
- 3 to validate or contradict them.
- 4 BY MR. ROTH:
- 5 Q. And did one of the clinical
- 6 experts review this part of your report and
- 7 give you feedback?
- 8 A. That review was done through
- 9 counsel.
- Q. Do you know which clinical
- expert reviewed your report and endorsed the
- 12 80 milligrams morphine equivalent for the
- daily dose for hospice patients?
- 14 A. I believe that both
- Dr. Schumacher and Dr. Parran reviewed this
- section of my report, specifically to look at
- the assumptions.
- 18 Q. If you look at e977 of the same
- ¹⁹ article.
- A. Sorry, you're still on there.
- Q. We're still on Haider.
- A. Sure.
- Q. So on the second column, last
- paragraph, it says: Despite a robust
- dataset, there are several limitations to

- this study. First, patients were treated at
- a comprehensive cancer center where dedicated
- palliative care services are available.
- 4 Hence, data from this single institution
- 5 cannot be generalized to other clinical
- 6 settings such as community-based programs.
- 7 Do you see that limitation?
- 8 A. I do.
- 9 Q. And is that something you
- 10 considered when deciding this was the study
- 11 to rely on?
- 12 A. Well, again, because I was
- seeking an estimate associated with
- palliative care, end-of-life care in
- particular, I don't think that limitation
- would pertain to my use of dosing from this
- study. I, of course, can't know what's in
- the authors' minds, but I think what they're
- 19 talking about is about treatment patterns,
- and a cancer center may be different than
- less well organized cancer treatment.
- Q. So you think when the authors
- 23 say data from the single institution cannot
- be generalized to other clinical settings,
- they mean data from the single institution

```
1
     can be generalized to hospice patients?
2.
                   MR. SOBOL: Objection.
3
            Α.
                   That is not what I said, but,
4
     for example, they are looking at prescribing
5
     patterns across molecules and not just
6
     dosages, and so it may well be that the kind
7
     of prescribing over time that patients get in
8
     a cancer center is different.
9
                   The -- it's not immediately
10
     obvious to me why dosing in a cancer center
11
     would be different than dosing in -- outside
12
     of it.
              There may be some difference.
                                              It's
13
     always true that any article relies on a
14
     particular dataset, and they will all say
15
     that you can't generalize outside of that
16
     dataset.
17
     BY MR. ROTH:
18
                   And we've been over this, but
            0.
19
     you're not an oncologist, correct?
20
            Α.
                   I'm not an oncologist.
21
                   So to ascertain the differences
22
     between treatment in a cancer center versus
23
     hospice, you would just be speculating as to
24
     what that might be?
```

MR. SOBOL: Objection.

25

- A. Well, I am a health economist
- who has worked on cancer treatment as the
- subject of some of my research, so -- so yes,
- 4 I don't know exactly what differences the
- 5 authors had in mind, but I can make an
- 6 informed speculation.
- 7 BY MR. ROTH:
- Q. Informed speculation. That's a
- ⁹ good one.
- 10 A. Yes.
- 11 Q. Is that more admissible than
- 12 normal speculation?
- MR. SOBOL: Sounds like to me.
- 14 THE WITNESS: Absolutely.
- Speculation with a Ph.D.
- MR. SOBOL: Shouldn't have
- asked that.
- 18 BY MR. ROTH:
- 19 Q. So then if we look at
- paragraph 96, we talked about the duration,
- you said 64 days.
- 22 A. Yes.
- Q. And you say you chose 64 days
- because it's just below the average number of
- days spent in hospice, which is 70.

- 1 A. Well, I chose 64 days from
- another article. I didn't choose 64 as
- arbitrarily just below 70 days. I'm sorry if
- 4 you read that sentence that way.
- Q. Yeah. I mean, it says 64,
- 6 which is just below the average number of
- days. I was trying to figure out why you
- 8 didn't pick 69 or 68 or 70 itself.
- 9 A. I apologize for the lack of
- 10 clarity. If you go back to footnote 125, the
- second article by Wachterman, et al.
- 12 Q. That one has 64 days?
- 13 A. That's the length of stay
- 14 article, yes.
- Q. And what did the Carlson
- article or the website you cite report as the
- average length of stay?
- 18 A. Right. So the 64 days comes
- from the Wachterman article. The 70 comes
- from the website.
- Q. And why did you choose to
- credit Wachterman's article over the average
- from the National Hospice and Palliative Care
- Organization website -- or research, I should
- 25 say.

```
1 A. Sure. Because not every
```

- patient at the end of life is in hospice, so
- the -- the data in the Wachterman article
- are -- they -- sorry.
- 5 What I mean is not every
- 6 patient in the second set of statistics has
- 7 cancer, whereas the Wachterman article has a
- 8 cancer subpopulation in it, so it's just more
- 9 precise. They're very similar. The
- difference would be about a 10% difference.
- Q. And I assume you'll tell me
- that that's captured in your 50% sensitivity
- 13 analysis.
- A. Well, that I can tell you, 10%
- is definitely less than 50%.
- 0. And what did the Carlson
- article say the average length of stay was?
- 18 A. I actually don't recall looking
- at the length of stay in the Carlson article.
- 20 Q. Okay.
- A. We can look at it.
- Q. So now we're going to do math,
- which is a little dangerous for me, but we're
- 24 going to try it.
- So for one patient receiving

- end-of-life cancer pain, your two assumptions
- of 64 and 80 MMEs would get you to 5,120
- 3 MMEs?
- 4 A. Okay. I also can't do math
- 5 without at least a pen.
- Q. We have an iPhone, so let's try
- 7 it.
- A. Let's try it.
- 9 Q. This is the best deposition
- 10 tool I've found. So 64 times 80 is 5,120.
- 11 A. Great.
- 12 O. And so to calculate the total
- 13 number of --
- MR. SOBOL: How does she know
- you just didn't type in 5,120?
- MR. ROTH: She can do it if she
- wants.
- THE WITNESS: He has an honest
- 19 face.
- MR. SOBOL: Go ahead. Sorry.
- BY MR. ROTH:
- 22 O. To calculate the total number
- of MMEs associated with end-of-life cancer
- patients and hospice care for cancer
- patients, you multiplied the number of cancer

- deaths each year by 5,120 MMEs?
- A. Yes. And just to be clear, you
- added "and hospice," but I'm very clear that
- 4 I'm calculating treatment for end-of-life
- 5 cancer patients.
- Q. Right. Right. And you're not
- 7 calculating at all for other hospice
- patients, which is the conversation we just
- 9 had.
- 10 A. That's correct.
- 11 Q. And then where do you get the
- number of cancer deaths from, which of the
- datasets is that?
- A. So that comes, excuse me, from
- 15 the SEER data.
- Okay. So then the next
- category you calculate potentially acceptable
- 18 MMEs for are patients with acute pain.
- A. Uh-huh.
- Q. And on page 66, and that's
- subdivided into trauma patients and surgical
- patients.
- A. Correct.
- Q. You don't consider any other
- type of acute pain?

- 1 A. That's correct.
- Q. So acute pain related to labor
- and childbirth would not be something that
- 4 opioids are appropriate for?
- 5 A. Well, I'm not a clinical expert
- but I have actually not heard of people using
- ⁷ opioids for labor pain.
- Q. What about for pain associated
- 9 with a cesarean section?
- 10 A. I'm not a clinician, so I think
- we shouldn't go there.
- 12 O. What about for nontraumatic
- injuries causing acute pain? Those aren't
- captured by your analysis, correct?
- A. Well, the -- we can go through
- in the technical appendix exactly which
- diagnosis codes are captured, so I'm not sure
- what you're referring to as nontraumatic
- injuries, but I think we should probably look
- 20 at Attachment D.
- Q. Okay. Let's do that. So where
- in Attachment D should we go?
- A. Okay. Let's -- I'm starting on
- page -- as opposed to table -- D8 and working
- my way over, so for the clinical

- 1 classification codes, we include our external
- causes of injury except for poisoning,
- overexertion, suffocation, adverse effects of
- 4 medical care and drugs and other or
- 5 unspecified causes.
- Q. So let me pause there.
- 7 I assume you -- well, maybe I
- 8 shouldn't assume. Let me just ask.
- 9 Why do you take out the
- categories of poisoning, overexertion,
- suffocation, adverse effects of medical
- care/drugs and other or unspecified causes?
- 13 A. Yes. I -- from what my
- understanding of the definition of
- appropriate uses under acute pain from the
- quidelines, these would not fit that
- 17 category. And again, the underlying
- assumptions were shared with clinicians.
- 19 Q. This does lead me to a question
- I meant to ask you earlier.
- Do your models, direct or
- indirect, include any opioid used to treat
- opioid use disorder, like naloxone or
- Suboxone, or were those taken out?
- A. Those were taken out.

- Q. Okay. So in this analysis, you
- include all of the IDC-9 trauma codes except
- for the one specified on page D9?
- 4 A. That's correct.
- 5 Q. And apart from what you told me
- 6 that the clinicians stated these would not be
- appropriate uses of opioids, you did not have
- 8 any other basis for excluding them from your
- 9 trauma numbers?
- 10 A. Well, I'm not a clinical
- expert, but I would say, on the face of it,
- the notion that opioids would be appropriate
- for adverse effects of medical care or drugs
- or poisoning is not something I would expect
- to be true, but I'm not a clinical expert, so
- 16 I certainly use my judgment as a starting
- point.
- Q. And certain opioids like
- Suboxone or naloxone might be, but are those
- taken out of this simulation as well?
- A. They are not in my analysis.
- Q. Okay. So back to paragraph 98.
- A. Yeah, way back.
- Q. So essentially, to measure the
- incidence of trauma, you use the data with

- the codes removed as specified in
- 2 Attachment D?
- A. That's correct.
- 4 Q. And you assume that a hundred
- 5 percent of those patients are treated with
- 6 opioids?
- 7 A. That's correct.
- Q. And then you assume, according
- 9 to paragraph 98, that each of these patients
- is treated with 30 MMEs of immediate-release
- opioids for three to seven days?
- 12 A. Correct.
- Q. And for that statement, it
- looks like you are relying on a white paper
- from the American Academy of Emergency
- Medicine, and then the CDC guidelines that we
- reviewed earlier. Or is it just from the
- 18 AAEM white paper?
- 19 A. I think they agree on these
- points.
- Q. Okay. So let's look at the
- 22 AAEM white paper, which I'll mark as
- 23 Exhibit 26.
- 24 (Whereupon, Deposition Exhibit
- Rosenthal-26, AAEM White Paper on

```
1
            Acute Pain Management in the Emergency
 2.
            Department, was marked for
 3
            identification.)
 4
     BY MR. ROTH:
 5
                   And this is the white paper you
            0.
 6
     rely on as support for using 30 milligrams
 7
     for three to seven days for trauma patients.
 8
                   You've printed it very small,
            Α.
 9
     so --
10
                   I did not, but someone did, and
            Q.
11
     I apologize.
12
            Α.
                   That's okay.
13
                   Do we need a magnifying glass?
            Ο.
14
                   I'm not bothering your glasses.
            Α.
15
     I'm going to hold it two feet in front of me.
16
                   Well, then my next question is
17
     going to be particularly hard for you to
18
     answer.
19
                   MR. SOBOL: Is there a footnote
20
            on this?
21
     BY MR. ROTH:
22
                   I was going to ask where you
23
     see the 30 milligrams of an immediate-release
24
     opioid such as hydrocodone, because I didn't,
     but you may not be able to see even the text,
25
```

```
1
     so that might be a bigger problem.
2.
            Α.
                   Yeah, I'm -- I believe the
3
     guidelines -- some of the guidelines say
4
     start at the lowest possible dose. I'm not
5
     sure the 30 milligrams is in this guideline.
6
                   I believe that they all say use
7
     immediate release. Here, the second bullet
8
     under Upon Discharge From the ED: Emergency
9
     medicine clinicians should prescribe only
10
     immediate-release formulations at the lowest
11
     effective dose and for the shortest course,
12
     generally two to three days' supply.
13
                   I think the CDC quidelines say
14
     three to seven.
15
     BY MR. ROTH:
16
                   And is the 30 also in the CDC
17
     quidelines or is that somewhere else?
18
                   I don't think it actually is,
            Α.
19
     and when I referred clinicians to this
20
     language, around the lowest effective dose, I
21
     believe that the 30 milligrams comes from
22
     getting a translation from clinical experts
23
     of what that lowest effective dose is.
```

Okay. So that's clear now.

So now as I understand it, your

Q.

24

25

- assumption for 30 morphine milligram
- equivalents for trauma patients comes from
- Dr. Parran and Dr. Schumacher telling you
- 4 that's what you should use?
- 5 MR. SOBOL: Objection.
- A. There's some other quidelines
- that we'll get to around surgery that have
- 8 some more specific doses, where I had those
- 9 numbers to say, you know, should I use one of
- these. But they're not in this document.
- We'll get to them in the next section.
- 12 BY MR. ROTH:
- Q. So for trauma, your dosage
- assumption comes from plaintiffs' experts?
- 15 A. It is -- yes. The -- the
- assumption, again, I did -- I used the
- quidelines to have that qualitative
- assumption, and I required assistance from
- 19 clinical experts to make sure that I
- understood how to translate that.
- But there were other guidelines
- that had some quantitative starting points,
- but not in these ones.
- Q. And when you say clinical
- experts, that's Drs. Schumacher and Parran?

- 1 A. That's correct.
- Q. So for one patient receiving
- treatment for trauma in an emergency room
- 4 setting, you assume 210 MMEs, which is 30
- 5 times the 7?
- A. And which we do without a
- ⁷ calculator, yes.
- Q. That's true.
- 9 And so to calculate the total
- number of MMEs for all patients who visited
- an emergency room for trauma, you multiplied
- the patients in the data times 210?
- 13 A. The patients in the data times
- 14 210, yes.
- Q. With the patients in the data
- being the page D9 description of which
- patients you looked at for trauma?
- 18 A. That's correct.
- Q. Okay. So now let's talk about
- surgery, which is paragraph 99. So to
- identify patients treated with opioids
- related to surgery, you say the universe is
- patients who underwent surgery on either an
- inpatient or an outpatient basis.
- A. That's correct.

```
1
                   And according to studies
2.
     published around the time of the alleged
3
     misconduct, 41% -- sorry. Let me reread
4
     that.
5
                   According to studies published
     around the time the alleged misconduct began,
6
7
     41% of postsurgical inpatients experienced
8
     moderate to severe pain.
9
                   Did I read that correctly?
10
                   Yes, you did.
            Α.
11
                   What do you mean by the time
            Q.
12
     the alleged misconduct began?
13
                   Again, where I reference
14
     literature on undertreatment -- well, it's
15
     upset, so now I have to go back. I was
16
     looking for literature that predated the
17
     alleged misconduct, so that -- I just have to
18
     see where I first cite the Marks and Sachar
19
     paper in that footnote 117. So those are the
20
     studies that we talked about at the very
21
     beginning of this analysis.
22
                   Is there any allegation that
23
     you're aware of that the alleged misconduct
24
     influenced the prescribing of opioids for
25
     surgical patients?
```

```
1
                   MR. SOBOL: Objection.
2.
                   I -- as I understand the
           Α.
3
     misconduct, the misinformation would affect
4
     the treatment of patients being discharged
5
     from surgery like any other patients, yes.
6
     BY MR. ROTH:
7
                   So in your view, discharging
8
     patients from surgery with opioid
9
     prescriptions beyond those prescriptions that
10
     you classify as potentially acceptable would
11
     be something that plaintiffs are trying to
12
     recover for?
13
                   MR. SOBOL: Objection.
14
                   Well, it sounds like there's
           Α.
15
     both a clinical and nonclinical opinion
16
     there, but again, remember this analysis is
17
     not decomposing actual use but trying to
18
     build up to a set of uses that according to
19
     clinical experts could have reasonably
20
     consumed opioid quantities over this period.
21
                   So again, we're not -- we're
22
     not sort of looking at what was done and
23
     parsing between appropriate and
24
     inappropriate. Just say, okay, well, there's
25
     going to be a set of people with surgery, and
```

- those people surely will have opioid use for
- some period of time. What would it look like
- if they all got treated.
- 4 BY MR. ROTH:
- 5 Q. So in paragraph 99, you again
- 6 come up with 30 MMEs and seven days for
- ⁷ surgery.
- 8 A. Yes, that's correct.
- 9 Q. So same as trauma?
- 10 A. Yes, the guidelines are quite
- 11 similar.
- 12 O. And for that conclusion that 30
- 13 MMEs each day is appropriate, you cite the
- MD Anderson Cancer Center Postoperative Pain
- Management Guidelines.
- 16 A. That's right. So that's the --
- the document that I mentioned did have some
- quantitative benchmarks in it.
- 19 (Whereupon, Deposition Exhibit
- Rosenthal-27, MD Anderson Cancer
- 21 Center Postoperative Pain Management
- Guidelines, was marked for
- identification.)
- 24 BY MR. ROTH:
- Q. So let me mark as Exhibit 27

- the MD Anderson Cancer Center Postoperative
- Pain Management Guidelines.
- And is this the document you
- were citing in your report?
- 5 A. It is.
- 6 O. So it looks like this was
- approved, if you look at the bottom of the
- page, on October 30th, 2018.
- 9 A. Yes, that's correct.
- Q. And are you aware that the
- algorithm used by MD Anderson to evaluate
- doses of pain management is what was used to
- come up with the dosage number? Strike that.
- 14 That's not a good question. Let's just turn
- 15 to page 3.
- A. Okay. At some point, I would
- direct you to page 10, but we can go to
- page 3 first.
- Q. Okay. We will get to page 10,
- I promise. It's in here.
- A. Okay. Good.
- Q. So it looks like they have sort
- of like a decision tree flow as to how
- they're going to come up with dosing for
- surgical patients, based on pain score.

- 1 A. That's right.
- 2 O. And it identifies different
- types of pain and the recommended treatment
- 4 options.
- 5 A. Yes.
- 6 Q. So if you look at page 5,
- 7 Appendix A describes the pain score, and it
- 8 may or may not have highlighting on it.
- 9 A. It does. I appreciate the
- 10 highlighting.
- 11 Q. Now you can see where we're
- going.
- A. That's great.
- Q. So if you look at page 5 in
- Appendix A, it says no pain is zero, mild is
- 16 1 to 3, moderate is 4 to 6 and severe is 7 to
- 17 10.
- Do you see that?
- 19 A. I do.
- Q. And then if you go back to
- ²¹ page 3.
- A. To page 3, okay.
- Q. So for patients with a pain
- score of less than 3 who are not currently
- taking opioids, they recommend using

nonopioids or weak opioids. 1 2. Do you see that? 3 Α. Yes. 4 Q. And then for opioid treatment 5 they refer to Appendix E, which is page 10, which we'll talk about in a minute. 6 7 Α. Okay. 8 Ο. Correct? 9 Α. Yep. For patients with a pain score 10 Q. 11 less than 3 who are currently taking opioids, 12 MD Anderson recommends continuing the use of 13 opioids and again refers to Appendix E. 14 Α. Yes. 15 For patients with a pain score 16 greater to or equal than 4 and who are not 17 taking opioids, MD Anderson recommends 18 short-acting opioids. 19 Do you see that? 20 I do. Α. And again refers to Appendix E, 21 Ο. 22 correct? 23 Α. Yes. And then for patients with a 24 Q. 25 pain score greater than or equal to 4 who are

- currently taking -- who are not currently
- taking opioids, MD Anderson recommends
- 3 short-acting opioids -- we just did that one.
- 4 Okay. Strike that. I'm getting tired.
- 5 For patients with a pain score
- greater than or equal to 4 who are currently
- taking opioids, MD Anderson recommends
- 8 increasing the scheduled opioid dose.
- 9 A. Yes.
- Q. All right. So now let's go to
- 11 Appendix E on page 10. And we've
- conveniently highlighted this for you.
- So if you look at
- 14 hydrocodone --
- A. Yes.
- Q. -- it recommends 30 milligrams
- a day, right, 5 to 10 milligrams every six
- 18 hours?
- 19 A. Yes. So 5 would be 20, right?
- Q. Sorry, let me back up the
- 21 truck. Okay. This is wrong.
- A. Yes.
- Q. So first we need to look at
- codeine, which is on the top of the page. So
- for codeine, it recommends 30 to

- 1 60 milligrams.
- Do you see that?
- A. Yes. I did not consider
- 4 codeine in the simulation per se, but go
- 5 ahead.
- 6 Q. Okay. And now if we look at
- 7 hydrocodone, it says for short-acting
- 8 opioids, it's 5 to 10 milligrams every six
- 9 hours.
- 10 A. Correct.
- Q. Which if we do the math on that
- would be between 20 to 40 a day.
- A. Yes. And 30 is right in the
- 14 middle.
- Q. Okay. And for long-acting
- opioids, 20 milligrams a day of Hysingla or
- 10 milligrams every ten hours.
- 18 A. I think in the flowchart we
- just looked at -- and again, according to
- clinical experts in this case, long-acting
- opioids are not recommended.
- Q. Right. So it's 20 to 40 for
- immediate-release hydrocodone?
- A. That's right, and 30 is in the
- middle of that.

- 1 Q. It's the average.
- A. It's the midpoint, it's the
- ³ average. Yes.
- 4 Q. But then if you look at
- morphine, which is on the next page, that's
- 6 also a short-acting opioid?
- 7 A. Yes.
- Q. And it's 5 to 10 milligrams
- every four hours, which by math would get you
- 10 30 to 60.
- 11 A. Yes.
- 12 Q. So I quess what I'm trying to
- understand is how you get to 30 when one
- range is 20 to 40 and the other range is
- 15 all -- is 30 to 60.
- A. Sure. Again, that's why --
- because the guidelines don't give one number,
- 18 I referred this question to the clinical
- experts through counsel, and -- and was
- advised to focus on hydrocodone and was told
- that 30 milligrams was a reasonable baseline.
- Again, assuming that there's
- some patients who will only get 20, some
- patients who will get more.
- Q. So again, like with trauma for

- surgical pain, your decision to take 30
- 2 morphine milligram equivalents per day was
- driven by plaintiffs' experts' advice?
- A. And it's grounded in these
- 5 guidelines. And again, while the other
- 6 quidelines that we looked at are qualitative
- in nature, as I understand the notion of
- 8 starting with the lowest dose, that seems
- 9 quite consistent with choosing 30.
- Q. And so like with trauma, 30
- times seven is 210, and then you multiply 210
- for surgery with the number of surgical
- patients in the data?
- 14 A. That's correct.
- Q. And then we should maybe just
- close the loop on this. So if we go back to
- the Attachment D.
- 18 A. Sure.
- 19 Q. Just to understand what data
- you're looking at for surgery.
- A. Yeah.
- Q. So it looks like page D10.
- A. Oh, you're in -- it's page D14.
- I think we're on the same page. Aren't we?
- Q. Page D10 talks about surgery.

- 1 A. Oh.
- Q. Page D14 is surgery in Cuyahoga
- 3 and Summit.
- 4 A. I see. I was ahead of you.
- We'll get to that, I'm sure.
- O. Yes.
- 7 A. Yes. Yes. So Table D(b),
- 8 which is also terrible labeling.
- 9 Q. Yes, so Table D(b) explains how
- you identified surgical procedures, and it
- says they're identified from the Area Health
- Resource File and the Health Resources &
- 13 Services Administration data.
- Do you see that?
- A. Yes, that's correct.
- Q. But then data was only
- 17 available for 2005, 2010 and 2014?
- A. That's correct.
- Q. And so you had to linearly
- interpolate all the other values.
- A. Yes, and as you can see, they
- 22 barely change.
- Q. But in any event, you only had
- data for three years, and so the rest of it
- was interpolated with the data that you had?

1 Α. I did interpolate. 2. Okay. And so if you go back to Ο. the body of your report, Table 6, which is at 3 4 page 70, essentially presents the math 5 exercise we've been talking about, correct? 6 Α. That's correct. 7 It has kind of the cancer, Ο. 8 trauma and surgical MMEs by year from 1995 to 9 2018 based on the inputs and assumptions 10 we've been discussing. 11 Α. Yes. 12 And so according to Table 6, 13 just looking at 1995, for example, there were 14 MMEs potentially clinically 15 justifiable? 16 Α. Yes. 17 Ο. And then the next column is 18 your sensitivity where you just multiply that 19 number by 50%? 20 Α. Correct. And so for 1995, your 21 22 sensitivity shows -- sorry, 23 -- start over. 24 For 1995, your sensitivity 25 shows MMEs were potentially

- 1 clinically justifiable with the 50% increase?
- A. Yes.
- Q. And that's actually higher than
- 4 the actual MMEs sold in that year?
- 5 A. That's correct. So that first
- 6 number should be a negative.
- 7 Q. The first number should be a
- 8 negative? I'm not sure I follow.
- 9 A. Well, of the total plus 50%, I
- guess the first -- the percentage there is of
- the -- of the unadjusted one, so it's
- 12 correct, but --
- Q. Yeah, it's correct. And
- 14 what --
- 15 A. It actually would be negative
- if you did the plus 50%.
- Q. Right. Okay. Thank you for
- that clarification.
- 19 A. It shows up in the chart more
- clearly.
- Q. And actually, if we just look
- at '95 alone, even under your methodology,
- 75% of the actual MMEs sold -- or nearly 75%,
- would be potentially clinically justifiable?
- 25 A. Could have been accounted for

- justifiable use by -- by justifiable uses,
- right? So again, just to be clear that I'm
- not saying that 75% of actual uses were --
- 4 were delivered in that way, but they could
- 5 have been.
- The level of use was reasonably
- 7 explained by this measure of need, if you
- 8 would allow me to use that shorthand.
- 9 Q. And so if you use your
- potentially justifiable use methodology,
- including your 50% sensitivity analysis, it's
- not until 1997 that you start seeing more
- than a small departure from the actual MMEs
- sold?
- A. Right. So in 1997, the actual
- is about higher than the -- those
- justified by need.
- Q. And then where is this actual
- 19 MMEs sold number coming from? The IQVIA data
- it looks like? It says: Actual MMEs
- 21 nationally from IQVIA, NPA, ARCOS, CDC.
- (Clarification requested by the
- reporter.)
- MR. ROTH: Okay. Sorry.
- BY MR. ROTH:

- 1 Q. The note on this chart is
- confusing to me because it says: Actual MMEs
- nationally from IQVIA, NPA, ARCOS and CDC.
- 4 A. The actual MMEs comes from
- 5 IQVIA. The CDC part relates to the MME
- translation. As I sit here, I cannot think
- of a reason that the ARCOS data are used in
- 8 the actual MMEs sold.
- 9 MR. SOBOL: Choice of drugs.
- 10 BY MR. ROTH:
- Q. We may have found another
- 12 errata.
- A. No, it's more likely that I
- just can't remember that detail as I sit
- 15 here.
- Q. Okay. And then if you look
- at -- so you've got the chart, and then the
- next few paragraphs -- or the next paragraph,
- 19 102 on page 71, says --
- 20 A. Yes.
- Q. -- The analysis described above
- can be applied at the county level. Table 7
- shows comparable results for the bellwether
- counties.
- Do you see that?

1 Α. Yes. 2. And so then you've got a Ο. 3 Table 7 with the counties. 4 How was the translation of the 5 national analysis to the counties done? 6 Α. So beginning with the number of 7 patients in each category, there are 8 county-level data available both on cancer deaths and from the Area Health Resource 10 File, where the surgical cases come from, for 11 the trauma patients they're allocated 12 according to population. 13 And who did that translation? Ο. 14 Α. That would be my staff at GMA. 15 Would you agree that opioids 0. 16 that plaintiffs' experts believe were 17 clinically justifiable are less likely to 18 cause overdose deaths? 19 MR. SOBOL: Objection. 20 I do not know the answer to Α. 21 that question, and again, this is a 22 simulation about what might have been a 23 clinically reasonable increase in opioid use. 24 It is not an assessment of 25 whether, in fact, in these counties or in the

- nation as a whole these uses were present in
- the way that I simulate them.
- 3 BY MR. ROTH:
- 4 Q. And I think we did talk about
- 5 this earlier during the course of the last
- two days, but you don't have any mechanism
- ⁷ for translating your calculation of
- 8 potentially justifiable MMEs in your thought
- 9 analysis to either of your regression models?
- 10 A. Well, maybe I'm getting tired,
- but I'm not sure I understand that statement
- in the form of a question or question in the
- form of a statement. So how would I
- translate this to my regression model?
- Q. Your regression models don't
- remove from the impact of defendants'
- promotion the clinically justifiable MMEs you
- calculate in your last opinion?
- A. Again, I simulate them. I'm
- not identifying them as actually having
- occurred. And the purpose of my direct and
- indirect analysis is to quantify the impact
- of alleged misconduct, whether it resulted in
- a clinically justifiable use or otherwise.
- Q. Okay. Did you review or rely

- on Dr. Kessler's report in this case?
- A. I did not review or rely on it
- prior to filing my report.
- Q. Do you know who Dr. Kessler is?
- 5 A. I do.
- Q. Have you seen him testify in
- other cases you've been involved in?
- 8 A. I think he has testified in
- other cases I'm involved with. I want to say
- that one of the -- one of my old reports that
- you put in front of me somehow mentioned him.
- But I certainly know who he is,
- and I believe he has testified in other cases
- I've been on, but I've not seen him testify.
- Q. I'm trying to streamline
- simultaneously.
- 17 A. That's fine. Take your time.
- Q. Do you agree with the statement
- that it is not a drug by itself that is
- regulated or that receives approval from the
- FDA; it is a drug for an intended use that is
- reviewed and approved by the FDA?
- A. Well, again, as a layperson,
- not an FDA expert, I do understand that drugs
- are approved for specific uses.

```
1
                   All right. And we talked a
            Ο.
 2.
     little bit at the beginning of your
 3
     deposition and a couple of other times about
 4
     drug labels, so I just want to show you one
 5
     for now.
 6
            Α.
                   Sure.
 7
                   (Whereupon, Deposition Exhibit
 8
            Rosenthal-28, Kadian Instructions for
 9
            Use, was marked for identification.)
10
     BY MR. ROTH:
11
                   And refresh me. I think you
            Ο.
12
     said you did not review any -- I think that's
13
     wrong. I think you said you'd seen maybe the
14
     hydrocodone and OxyContin drug labels?
15
            Α.
                   I specifically remember seeing
16
     those, reviewing those at some point during
17
     my analysis.
18
                   But you did not do a
19
     comprehensive review of all the drug labels
20
     for all of the opioids at issue in this case?
21
                   MR. SOBOL: Objection, asked
22
            and answered.
23
            Α.
                   I did not systemically analyze
24
     the drug labels.
25
                   ///
```

```
BY MR. ROTH:
 1
 2.
                   All right. I'm going to mark
            Q.
 3
     as Exhibit 28 the drug label for Kadian.
                   I really am going to have to
 4
 5
     get glasses.
                   I apologize, these are printed
 6
            0.
 7
     so small.
 8
                   Do you know what Kadian is?
 9
            Α.
                   I'm aware that it's in this
10
             I have -- I think I cite to some
11
     documents involving Kadian in my report.
21
                   So if you look at the top of
22
     the first page, Kadian is a morphine sulfate
23
     extended-release capsule.
24
                   Do you see that?
25
            Α.
                   Yes.
```

```
1
            0.
                   And there's a big black box on
     the left side of the front page.
 2.
 3
                   Do you see that?
 4
            Α.
                   I see the black box.
 5
                   And in all capital letters at
            Ο.
 6
     the top of the box it says: Warning:
 7
     Addiction, abuse, and misuse; risk evaluation
 8
     and mitigation strategy, REMS;
     life-threatening respiratory depression;
 9
10
     accidental ingestion; neonatal opioid
11
     withdrawal syndrome; interaction with
12
     alcohol; and risks from concomitant use with
13
     benzodiazapines or other CNS depressants.
14
                   Do you see that?
15
            Α.
                   I see that.
16
                   And that's in all capital
            Ο.
17
     letters.
18
            Α.
                   It is.
19
            Ο.
                   And then there are seven
20
     bullets in all bold that follow underneath in
21
     that same black box.
22
                   Do you see that?
23
                   I do.
            Α.
                   And have you read a black box
24
25
     warning like this one before?
```

1 Α. I have. 2. In what context? Ο. 3 Α. Well, when we were talking --4 I'm -- I may have seen black box warnings in 5 this case. When we were talking about this 6 yesterday, I mentioned that black box 7 warnings were a part of the factual base for 8 the Zyprexa in other antipsychotic litigation I was involved in. 10 Have you done, or are you aware 11 of any research trying to ascertain whether 12 marketing convinces doctors to ignore black 13 box warnings such as the one in front of you? 14 MR. SOBOL: Objection. 15 Α. As I mentioned yesterday, I am 16 aware of research about black box warnings 17 and the instances in which they have not been 18 effective, and therefore, ignored by 19 prescribing physicians. 20 And in the antipsychotic 21 litigation I was involved in, I did some 22 analysis that showed that while there was a 23 short-run response to the black box warning, 24 that prescribing returned to its original

trend.

25

```
1
     BY MR. ROTH:
                   Which antipsychotic drug were
 2.
            Q.
 3
     you involved in?
 4
            Α.
                   Well, you know about Zyprexa --
 5
            Ο.
                   Right.
 6
            Α.
                   -- from the case you put in
 7
     front of me. I was an expert in several
 8
     Risperdal cases as well, and the black box
 9
     warning for atypical antipsychotics is common
10
     to all the second-generation drugs.
11
                   Okay.
                           If you look at the
            Q.
     section is labeled Indications and Usage on
12
13
     the same page below the black box warning?
14
            Α.
                   Yes.
15
                   It says: Kadian is an opioid
            Ο.
16
     agonist indicated for the management of pain
17
     severe enough to require daily
18
     around-the-clock long-term opioid treatment,
19
     and for which alternative treatment options
20
     are inadequate.
21
                   Do you see that?
22
                   I do.
            Α.
23
            Ο.
                   And that's the FDA-approved
     indication and usage?
24
25
                   MR. SOBOL: Objection.
```

- A. Again, as I understand the FDA
- label, it contains information on the
- approved usage. I'm not -- neither a
- 4 clinician nor an FDA expert. That is my
- 5 layperson's understanding.
- 6 BY MR. ROTH:
- 7 Q. Okay. And do you have any
- 8 reason to doubt that when the FDA approved
- 9 the label for Kadian or any other opioid
- involved in this case, that it underwent the
- 11 regulatory process required by federal
- regulations, including receiving studies of
- efficacy and safety?
- MR. SOBOL: Objection, scope.
- 15 A. I could not say one way or
- another. I don't have the information to
- evaluate such a proposition.
- 18 BY MR. ROTH:
- Q. Okay. Let's look at your
- report, paragraph 11, which was the summary
- of your opinions.
- A. Yes. Not the table, just the
- paragraph?
- Q. We can look at both.
- A. Okay.

- 1 Q. I think we've made it through
- 2 all of them now.
- A. Impressive.
- Q. There may be one we didn't, so
- 5 that's what I want to talk about.
- 6 A. Okay. Good.
- Q. If you look back at
- 8 paragraph 11, the second bullet in your
- 9 summary says -- well, the first bullet,
- 10 Promotion of pharmaceuticals increase their
- sales.
- We talked about that I think a
- 13 lot yesterday.
- 14 A. I think so.
- 15 Q. The second bullet. The alleged
- unlawful promotion of opioids, if proven,
- resulted in increased sales of opioids.
- We talked about that some as
- well.
- 20 And then if you look at the
- table, I think those opinions are captured by
- Section VI of your report; is that right?
- A. Section VI and VII generally go
- to the first bullet point, which is, you
- know, at a high level, promotion increases

```
1
     sales.
2.
                   I quess what I'm getting at is
3
     your econometric models are not cited as a
4
     basis for your opinions that either promotion
5
     increases sales or that the unlawful
6
     promotion, if proven, resulted in an increase
7
     in sales.
8
            Α.
                         So the econometric models
                   Yes.
9
     clearly show that the alleged unlawful
10
     promotion of opioids caused sales. I don't
11
     specifically cite to the econometric models
12
     there, but when I reach my conclusions from
13
     the models, we can go to that text, I do
14
     conclude that the model shows a causal
15
     relationship.
16
                   So even though I don't mention
17
     the econometric model specifically until I
18
     get to the next bullet point, the fact that
19
     I'm identifying the extent there is also
20
     premised on the existence of an effect.
21
                   Okay. I understand now.
            Ο.
22
                   So if you look at the second
23
     bullet point, the last sentence says:
24
     result, I am of the opinion that the combined
25
     effect of the defendant manufacturers'
```

- promotion of prescription opioids since 1995
- was a substantial contributing factor to the
- increase in the use of prescription opioids
- 4 in the bellwether communities.
- Did I read that correctly?
- 6 A. You did.
- 7 Q. And that is based largely on
- 8 the econometric models?
- 9 A. It's based on all the
- 10 foregoing.
- Q. Okay. And I noticed the way
- you worded that sentence was that the
- promotion was a substantial contributing
- 14 factor; is that right?
- A. That's right.
- Q. Not that the unlawful promotion
- was a substantial contributing factor,
- because as we've discussed, you have no
- opinion on whether defendants' promotion was
- unlawful or not; you're relying on counsel's
- 21 assumption.
- MR. SOBOL: Objection, asked
- and answered.
- A. Again, I -- perhaps I should
- have repeated the unlawful promotion, if

- proven. So as you say, I demonstrate that
- promotion caused sales, and I assume that
- 3 plaintiffs will prove that all promotion was
- 4 unlawful.
- MR. SOBOL: By the defendants.
- A. All promotion by the defendants
- 7 was unlawful.
- 8 BY MR. ROTH:
- 9 Q. And because you assumed that
- all promotion by the defendants was unlawful,
- that assumption would include promotion even
- if a sales representative only dropped off
- peer-reviewed literature at a doctor's
- 14 office?
- MR. SOBOL: Objection, asked
- and answered.
- A. My analysis includes all
- promotion by defendants. When I calculate
- the but-for scenario, I remove that
- regardless if some of that promotion used
- 21 materials that were FDA approved.
- 22 BY MR. ROTH:
- Q. Your analysis also includes
- promotion by defendants even if the sales
- representative had no interaction with the

```
1
     prescriber?
 2.
                   MR. SOBOL: Objection, asked
 3
            and answered.
 4
                   I think what you're suggesting
 5
     is that detailing may involve an interaction
     with someone else in the office? Is that
 6
 7
     what you're referring to?
                   And, yes, as I understand the
 8
 9
     matter at hand, that the entire promotional
10
     enterprise is what is at issue here, and so I
11
     have appropriately captured all detailing in
12
     my econometric model.
13
     BY MR. ROTH:
14
                   Your analysis includes all
            Ο.
     promotion by defendants even if that
15
16
     promotion did not result in any change in the
17
     prescriber's behavior after they were
18
     detailed?
19
                   Well --
            Α.
20
                   MR. SOBOL: Objection.
21
                   -- actually, I would
            Α.
22
     respectfully disagree with that. My analysis
23
     only attributes impact where promotion
     resulted in an increase in sales.
24
25
                   ///
```

```
BY MR. ROTH:
1
2.
                   But you include in your
            Ο.
3
     analysis details that may have had no effect
4
     on the particular prescriber's behavior?
5
                   MR. SOBOL: Objection, asked
6
            and answered.
7
                   And if that is the case, then
8
     it reduces the incremental effectiveness of
9
     promotion that I observe, and therefore, the
10
     calculated impact. The possibility that some
11
     details did not produce change is
12
     incorporated into the estimates.
13
     BY MR. ROTH:
14
                   You include in your analysis
            Ο.
     detailing where the prescriber's rate of
15
16
     prescription may have actually decreased
17
     after the detail?
                   MR. SOBOL: Objection, asked
18
19
            and answered.
20
                   My analysis will incorporate
            Α.
21
     the effects, negative or positive. Obviously
22
     on average they're positive. If there are
23
     some negative changes after a detail for some
24
     reason, those again will reduce the measure
```

of impact.

25

```
1 BY MR. ROTH:
```

- Q. You include in your analysis
- detailing even if the prescriber never
- 4 prescribed the medicine he or she was
- 5 detailed on?
- 6 MR. SOBOL: Objection.
- 7 A. Yes. Again, just like the --
- 8 any detailing that has no effect or a lower
- 9 effect, I quess that would be a version of no
- effect, if the individual detailed never
- prescribed. And again, that will reduce the
- impact of detailing in my model.
- 13 BY MR. ROTH:
- Q. You include in your analysis
- detailing to prescribers who were already the
- lead authors of journal articles on the
- addiction risk of opioids at the time they
- were detailed?
- MR. SOBOL: Objection.
- A. If there is such detailing in
- 21 my data, again, my estimates will
- 22 appropriately reflect a reduced effectiveness
- of promotion for those details.
- 24 BY MR. ROTH:
- Q. Your analysis includes

- detailing to oncologists prescribing for
- end-of-life cancer pain?
- A. Again, to the extent that my
- analysis does not grow the size -- sorry, to
- 5 the extent that promotion does not grow the
- size of the market by expanding the use of
- opioids, detailing, for example, to
- 8 oncologists who may already have been
- 9 prescribing opioids will not result in
- 10 impact.
- 11 Q. Your analysis includes
- detailing to prescribers who are hospice
- specialists for end-of-life pain.
- 14 A. To the extent that there is
- detailing to hospice providers in my data and
- those uses would have occurred regardless of
- the promotion, my analysis will appropriately
- capture those effects.
- 19 Q. Your analysis includes
- detailing to prescribers who may be
- 21 performing surgery or trauma intervention in
- the emergency room?
- A. Again, to the extent that
- those -- my analysis will calculate the uses
- that occurred in this market as a result of

- the alleged misconduct. Regardless of how
- those opioid prescriptions were used in
- practice, as I understand, is appropriate to
- 4 my assignment.
- 5 Q. Stated differently, your
- 6 analysis includes any detailing in the data
- 7 regardless of to whom it was -- let me start
- 8 over.
- 9 Stated differently, your
- analysis -- can we just get a clean question
- and answer. Say something.
- 12 A. Yes. What was the question? I
- don't know what the question is.
- Q. Stated differently, your
- analysis includes any detail in the data,
- regardless of who was detailed, what was said
- or what behavior changed or did not after the
- 18 detail?
- A. So my analysis is consistent
- with my assignment in that I examine and
- quantify the aggregate market expansion that
- occurred as a result of defendants' promotion
- during the period from 1995 to the end of my
- data in 2018. I do not disentangle the types
- of detailing; however, to the extent there

```
1
     are differential effects of detailing across
2.
     groups, those will be incorporated into the
3
     estimates.
4
                   MR. ROTH: Our time may be
5
                   Let's take a quick break. And
6
            I may have more questions or someone
7
            else may.
8
                   THE WITNESS: Okay.
9
                   THE VIDEOGRAPHER: The time is
10
            1:35 p.m. We're now off the record.
11
                   (Recess taken, 1:35 p.m. to
12
            1:51 p.m.)
13
                   THE VIDEOGRAPHER: The time is
14
            1:51 p.m. We're back on the record.
15
     BY MR. ROTH:
16
                   Professor Rosenthal, in Table 2
17
     you calculate the total percent of MMEs
     attributable to defendants' promotion to be
18
19
           of MMEs; is that right?
20
            Α.
                   That's right.
21
                   To what do we owe the other
            Ο.
22
           of MMEs?
23
                   The other -- excuse me --
24
     percent of MMEs are owed to the promotion
25
     that is not excluded in the but-for scenario,
```

- so again, because I start my data as early as
- I can in '93, there's a stock of promotion
- that builds up, and then there's
- 4 non-defendant promotion. So all those things
- 5 are left in the model.
- 6 Q. So it's promotion prior to '95
- by anyone and non-defendant promotion
- 8 thereafter?
- 9 A. That's correct.
- Q. And that explains of the
- 11 MMEs with the remainder being explained by
- defendants' promotion from 1995 to 2018?
- 13 A. That's generally correct. You
- know, there's a constant in the model, which
- 15 I think we could go to Table 1 and in
- Model B, so there's a baseline level of
- 17 MMEs.
- 18 Q. Okay.
- A. So that's in there as well.
- Q. And then the same question for
- the indirect model, you calculate of MMEs
- due to excess shipments, so is it fair to say
- based on your approach that the other is
- due to the demographic and socioeconomic and
- other factors you model for?

- MR. SOBOL: Objection.
- 2 A. That would be due to the
- 3 changes in all of those factors. Again,
- 4 price actually has a negative effect, but the
- 5 trend which is intended to proxy for
- 6 non-defendant promotion and those other
- demographic, socioeconomic and healthcare
- 8 variables.
- 9 BY MR. ROTH:
- Q. Okay. And then if you look
- back at page 19 of your report, Figure 1.
- 12 A. Sorry, excuse me. I should
- just say again, in the indirect model as in
- the direct model there's also a baseline,
- right, so we're projecting growth from '95
- forward. So there's a baseline level.
- 17 O. Got it.
- So if you look on Figure 1 on
- page 19, we haven't actually talked about
- this diagram yet.
- A. Okay. Page 19. Yes.
- Q. And is this a diagram you've
- used in other expert reports before?
- A. I tailored this one
- specifically for this report, but I have used

- similar kinds of diagrams.
- Q. And if we look at your diagram,
- you have the ecosystem of promotion in all of
- 4 the lines between the various constituencies,
- 5 and in the box in the middle, there's
- detailing, professional journals, samples,
- 7 and meetings and events.
- 8 Do you see that?
- 9 A. Yes.
- Q. And as we discussed, your model
- only accounts for detailing promotion, not
- for any of the other items in the box or any
- of the other boxes on Figure 1?
- MR. SOBOL: Objection,
- mischaracterizes the testimony, asked
- and answered.
- 17 A. The direct model includes the
- measure of detailing only. The indirect
- model is intended to capture all of these
- kinds of marketing tools.
- BY MR. ROTH:
- Q. And then Table 3, which we've
- been round and around on, to the extent that
- you used Table 3 to assess the delta between
- a defendant's promotion percentage and the

```
baseline percentage, that delta is capturing
1
2.
     how that defendant's promotion relates to the
3
     aggregate average; is that right?
4
                   MR. SOBOL: Objection, asked
5
            and answered.
6
           Α.
                   As we discussed earlier, I
7
     don't use the table in that way. I'm using
8
     it to narrow the aggregate by excluding
9
     individual defendants.
10
                   And when I do that, for
11
     example, to exclude Aventis, just as an
12
     alphabetically first choice, I am excluding
13
     ultimately the effect that I observe in the
14
     econometric model of Aventis' marketing,
15
     whether that generates sales for its product
16
     or someone else's product.
17
                   MR. ROTH: Okay. I think with
18
            that I am done for the time being.
19
            It's been a pleasure. I believe
20
           Mr. Metz has some questions, so I will
21
           be passing the microphone to him. And
22
            I can't promise I won't come back,
23
            depending on what else happens, but
24
            thank you so much.
25
                   THE WITNESS: Okay. Thank you.
```

```
1
                   THE VIDEOGRAPHER: The time is
2.
            1:56 p.m. We're now off record.
3
                   (Recess taken, 1:56 p.m. to
4
            1:58 p.m.)
5
                   THE VIDEOGRAPHER: The time is
6
            1:58 p.m. We're back on the record.
7
                       EXAMINATION
8
     BY MR. METZ:
9
              Good afternoon, Professor
           Q.
10
     Rosenthal.
11
           Α.
                  Good afternoon.
12
                   My name is Carl Metz.
           Q.
                                           Ι
13
     represent Cardinal Health, which is one of
14
     the distributor defendants in this case.
15
                   I apologize for forgetting the
           Α.
16
     name of your employer as it were.
17
           Q.
                   That's all right. You're
18
     referring to testimony yesterday where you
19
     were asked about the distributor defendants,
20
     you named two companies, and the third name,
21
     Cardinal, eluded you. Yes?
22
                   Exactly, yes.
           Α.
                   Okay. At various places in
23
           Ο.
     your report, you refer to marketing
24
25
     defendants, correct?
```

- 1 A. Yes, I do.
- Q. And then in other places, and
- I'm sure this is not by design, you refer to
- 4 the word "defendants" without
- 5 differentiation.
- 6 MR. SOBOL: Objection to the
- 7 form.
- You can answer.
- 9 A. Yes, I believe I use that term.
- We could look to see how I use it.
- 11 BY MR. METZ:
- Q. For example, in paragraph 64,
- which you're welcome to look at, and I'll
- quote this just partially. You say, quote:
- 15 A causal relationship between the
- defendants', possessive, promotion and
- prescriptions of opioids.
- Do you see that?
- 19 A. Yes.
- Q. And do I understand based on
- your testimony over the last two days that
- despite using the singular term "defendants,"
- we should not read that as referring to all
- defendants, correct?
- MR. SOBOL: Objection.

```
1
            Α.
                   In this paragraph in
2.
     particular, I'm talking about the defendants
3
     who have detailing that I'm measuring in my
4
     data, so those would be the marketing
5
     defendants.
6
     BY MR. METZ:
7
                   Okay. And by marketing
            Ο.
8
     defendants, you're not including any of the
9
     distributor defendants, correct?
10
                   I don't believe that they have
11
     marketing data in my data, so there may be
12
     places in my report where I refer to
13
     defendants where it's appropriate to talk
14
     about them more generally, for example, when
15
     I'm summarizing the complaint, but here I
16
     intend to describe the defendants who have
17
     detailing that is measured in the IQVIA data.
18
                   Okay. So just to be clear,
     not -- as you believe it, not -- that does
19
20
     not include the distributor defendants,
21
     correct?
22
                   MR. SOBOL: Objection, asked
23
            and answered.
24
                   I believe that is true.
            Α.
25
                   ///
```

```
BY MR. METZ:
 1
 2.
                   Okay. And it also does not
            Ο.
 3
     include the pharmacy defendants, correct?
 4
                   MR. SOBOL: Objection, asked
 5
            and answered.
 6
                   Yes, that is correct.
            Α.
 7
     BY MR. METZ:
 8
                   So we take another example,
 9
     paragraph 78, where you say, quote:
10
     alternative method of identifying the impact
11
     of the defendants', possessive, misconduct,
12
     is to use an indirect method.
13
                   Do you see that?
14
            Α.
                   Yes.
15
                   And there again, you're using
16
     the term "defendants," but how we should
17
     understand that is the marketing defendants,
18
     correct?
                   Well, the -- in -- excuse me,
19
20
     the indirect approach -- it is getting to be
21
     late -- is, as you know, a residual approach,
22
     so it inherently is looking at all of these
23
     demographic, socioeconomic and healthcare
24
     factors that could have driven higher opioid
25
     use and attributes that which is left to the
```

- 1 misconduct.
- I think it's a little bit less
- 3 clear about how that analysis might be used
- 4 to assess liability for distributors. I have
- 5 not been asked to do that, but the indirect
- analysis, because it's not measuring the
- 7 conduct of a specific group, could be open to
- 8 a broader interpretation.
- 9 Q. Have you disclosed any opinions
- that, based upon your indirect model, you
- draw conclusions about distributor
- defendants' conduct?
- 13 A. I have not. I have not drawn
- those conclusions.
- Q. And you mentioned the detailing
- data, but just to be clear, you did not
- include in your direct model any data series
- that you understood were measuring the
- conduct of the distributor defendants; is
- that correct?
- MR. SOBOL: Objection, asked
- and answered.
- A. I have not measured the conduct
- of the distributors or included that in my
- model.

```
BY MR. METZ:
 1
 2.
                   And the same would be true of
            Ο.
 3
     the pharmacy defendants, correct?
 4
                   MR. SOBOL: Objection, asked
 5
            and answered.
 6
            Α.
                   I have not measured the conduct
 7
     of the pharmacies and included that in my
 8
     models.
 9
                   MR. METZ: Just so it's not
10
            recurring, I'm five questions in.
11
            What have I asked and answered? Or
12
            what have I asked previously?
13
                   MR. SOBOL: All of this was
14
            covered by Mr. Roth this morning and
15
            yesterday.
16
                   MR. METZ: Okay. I disagree.
17
     BY MR. METZ:
18
                   You testified at several points
19
     that the design of your model is intended to
20
     capture an aggregate effect on MMEs sold,
21
     correct?
22
                   That's correct.
            Α.
23
            Ο.
                   And in part what that means is
24
     you've not reported your results in a way
     that allows you to identify any particular
25
```

- set of prescriptions that combine to make up
- the additional MMEs you've identified in your
- 3 analysis, correct?
- 4 A. The way my analysis works is to
- 5 analyze the actual data and identify a
- quantity of prescriptions in aggregate that
- 7 would not have been filled absent the
- 8 promotional misconduct.
- 9 As I noted yesterday, because
- the but-for scenario did not occur, we cannot
- explicitly observe which individual
- prescriptions would not have been filled. So
- there's a conceptual impossibility to the
- statement that you're describing.
- Q. Okay. So just to be clear,
- your answer is yes, but for the reason that
- it would be impossible?
- MR. SOBOL: Objection, asked
- and answered.
- 20 A. Yes, and my analysis -- as you
- know, my assignment was to estimate the
- impact of the alleged misconduct and to
- quantify that in aggregate.
- BY MR. METZ:
- Q. I understand. The alleged

- marketing misconduct, correct?
- 2 A. The alleged marketing
- 3 misconduct.
- 4 Q. And am I correct that the data
- 5 that you use in your calculation does not
- 6 contain identifying information for
- individual prescriptions, correct?
- 8 A. My data do not contain
- 9 individual prescription identifiers. I
- assume by that you mean something like a
- 11 member identifier.
- 12 Q. Anything that would enable you
- to identify a specific prescription that's
- within the sum of your conclusions?
- A. No. Again, because of -- for
- privacy reasons, my data are deidentified.
- Q. Okay. Now, you testified
- yesterday that you have not formed any
- opinions about the separate role of doctors
- in causing an increase in the MMEs that you
- measured.
- Do you recall that testimony?
- A. I believe I described the fact
- that of course doctors are in the causal
- chain, they're the ones writing the

- 1 prescriptions.
- Q. Right. You testified that
- the conduct you're attempting to measure
- flows through doctors, but you're not forming
- 5 a separate opinion about their independent
- 6 role in the causal chain, what influence they
- 7 exerted in the causal chain, correct?
- MR. SOBOL: Objection.
- 9 A. I have not separately examined,
- 10 I guess, doctor behavior. Again, because
- it's tautologically true that every
- prescription is written by a physician, I
- struggle with that concept.
- 14 BY MR. METZ:
- 0. I understand.
- Now, you also testified
- yesterday that you've not formed any opinions
- about whether any quantity of the increase in
- 19 MMEs identified in your opinions was
- medically necessary or unnecessary, correct?
- MR. SOBOL: Objection. On the
- direct model, you mean?
- BY MR. METZ:
- Q. On the direct model, do you
- recall that testimony?

- 1 A. Yes. In the direct and
- indirect models, I do not differentiate
- between medically necessary and unnecessary
- 4 prescriptions.
- 5 Q. Okay. And in part what that
- 6 means is you have not endeavored to identify
- any subset of your total measured MME
- 8 increase that consists of prescriptions that
- 9 do not meet an appropriate standard of
- 10 medical care; is that correct?
- MR. SOBOL: Objection, asked
- and answered.
- 13 A. I have not evaluated the -- nor
- am I a clinical expert, just to be clear --
- the medical necessity of any of the
- prescriptions that I find were caused by the
- 17 alleged misconduct.
- 18 BY MR. METZ:
- Q. Right. You've not done that at
- the level of individual prescriptions in the
- first instance, correct?
- MR. SOBOL: Objection, asked
- and answered.
- A. I have not done analysis at the
- level of individual prescriptions at all.

```
1
     BY MR. METZ:
 2.
                   Okay. And you've not done that
            Ο.
 3
     for an aggregate sum of prescriptions either,
 4
     correct?
 5
                   MR. SOBOL: Objection, asked
 6
            and answered.
 7
                   I have not evaluated medical
 8
     necessity of any prescriptions.
 9
     BY MR. METZ:
10
                   All right. Am I correct that
            Ο.
11
     you've also not undertaken to identify any
12
     subset of your total MME increase that
13
     consists of prescriptions a pharmacist should
14
     have refused to fill for whatever reason
15
     after it was presented by a patient?
16
                   MR. SOBOL: Objection.
17
                   I have not been asked to
            Α.
18
     examine the decisions of pharmacists or the
19
     conduct of pharmacists as it relates to this
20
     matter.
21
     BY MR. METZ:
22
                   Okay. So you've not done that
23
     for the reason you just stated?
```

MR. SOBOL: Objection, asked

and answered.

24

25

- 1 A. I have not examined the conduct
- of pharmacists.
- 3 BY MR. METZ:
- Q. Okay. And you're not an expert
- in what constitutes responsible conduct of
- 6 pharmacists, correct?
- 7 A. I'm not an expert in what
- 8 constitutes responsible conduct for
- 9 pharmacists.
- Q. Based on your role as a
- healthcare economist, are you, though,
- generally aware that pharmacists have certain
- obligations relating to the dispensing of
- 14 pharmaceuticals?
- 15 A. I am aware generally where
- pharmacists fit in the supply chain. I am
- not familiar with the specifics of their
- professional guidelines.
- Q. Okay. And recognizing that
- you've already told me you do not have the
- expertise to do this, it was not your
- assignment, and you do not have the
- visibility at the prescription level -- I
- just want to confirm for the record -- you
- have not evaluated whether individual

```
prescriptions that are somehow within your
total MME calculation were properly filled
from the perspective of a pharmacist?
```

- 4 MR. SOBOL: Objection.
- 5 Objection, asked and answered.
- A. I have not evaluated -- I quess
- 7 it sounds to me like you're just saying that
- 8 there's a notion of medical necessity that
- 9 applies to pharmacists, but I have not
- 10 evaluated the medical circumstances around a
- particular prescription, whether it pertains
- to the doctor's decisions or the pharmacist's
- decisions.
- 14 BY MR. METZ:
- Q. Thank you for that. And just
- to be clear, because that's not what I was,
- in fact, suggesting, I'm just trying to
- confirm what is not done within the contours
- of your opinions, not necessarily the reasons
- for them or suggesting that you should have
- done these things.
- MR. SOBOL: Well, she's going
- to give complete answers to the
- questions.
- MR. METZ: I don't mind her

```
giving complete answers.
 1
 2.
                   MR. SOBOL: Okay.
 3
     BY MR. METZ:
                   You similarly have not -- it
 4
            Q.
 5
     follows, I think, by not having done that
 6
     analysis at the level of individual
 7
     prescriptions, you've also not evaluated
 8
     whether individual pharmacists improperly
     dispensed in response to prescriptions they
 9
10
     were presented with, correct?
11
                   MR. SOBOL: Objection, asked
12
            and answered.
13
                   I have not evaluated the
            Α.
14
     conduct of individual pharmacists in my
15
     analysis.
16
     BY MR. METZ:
17
            Ο.
                   Okay. And you've not
18
     undertaken such an evaluation at the level of
19
     pharmacies as a whole, correct?
20
                   MR. SOBOL: Objection, asked
21
            and answered.
22
                   I have not evaluated the
            Α.
23
     contribution of pharmacies to these
24
     prescriptions.
25
                   ///
```

```
1 BY MR. METZ:
```

- Q. And you've not evaluated that
- at the level of chains of pharmacies,
- 4 correct?
- MR. SOBOL: Objection, asked
- 6 and answered.
- A. I have not evaluated the
- 8 conduct of pharmaceutical chains or pharmacy
- 9 chains to the opioid prescriptions.
- 10 BY MR. METZ:
- 11 Q. Now, in Table 2 of your report,
- you disclose some information on a percentage
- basis under a heading that it is the percent
- of MMEs attributable to challenged promotion,
- 15 correct?
- A. I think that's right. I'm
- sorry, just let me get the table. Percent of
- 18 MMEs attributable to challenged promotion,
- ¹⁹ yes.
- Q. Okay. Now, would I be correct
- in surmising that for all the reasons we've
- been discussing, it would not be correct to
- characterize the results reflected in Table 2
- as reflecting a percentage of MMEs prescribed
- in excess of legitimate medical need?

```
1
                   MR. SOBOL: Objection, asked
 2.
            and answered.
 3
            Α.
                   It is -- I do not describe my
 4
     calculations that way, and as we discussed
 5
     earlier, I have not evaluated the medical
     necessity of any prescriptions.
 6
 7
     BY MR. METZ:
 8
                   Okay. My question was close to
 9
     that, but it's not that.
10
                   They're not described that way,
11
     and it would be incorrect to describe them
12
     that way based on the analysis you conducted,
13
     correct?
14
                   MR. SOBOL: Objection, form,
15
            asked and answered.
                   I did not analyze medical
16
            Α.
17
     necessity. My results do not pertain to
18
     medical necessity and, like anything, they
19
     are not, it would be incorrect to label them
20
     medical necessity or anything else that they
21
     are not.
22
     BY MR. METZ:
23
            Q.
                   Thank you.
24
                   You would also agree with me
25
     that again, for the same reasons we've been
```

- discussing, it would not be correct to
- characterize Table 2 as reflecting a percent
- of MMEs dispensed by pharmacies or
- 4 pharmacists in excess of legitimate
- 5 prescriptions?
- 6 MR. SOBOL: Objection, asked
- and answered.
- A. I am not sure whether --
- 9 because I have not analyzed the conduct of
- pharmacists or pharmacies -- whether another
- expert might deem these same units that I
- calculate are caused by promotion to have
- been in excess from the point of view of the
- conduct of pharmacists or pharmacies.
- I have not done that analysis.
- So you're asking me a question about how
- these -- these analyses might be used by
- others, as far as I'm concerned.
- 19 BY MR. METZ:
- Q. I'm asking the author of the
- 21 analysis the proper interpretation of the
- 22 analysis, and as the author of the analysis,
- it would not be a proper interpretation that
- what this reflects is a quantity of opioid
- 25 pharmaceuticals dispensed in excess of

```
legitimate prescriptions, correct?
1
2.
                   MR. SOBOL: Objection, asked
3
            and answered, mischaracterizes prior
4
            testimony.
                   When you use the word
5
            Α.
     "legitimate," to me that sounds like it -- I
6
7
     mean, literally it's a legal term, and so
8
     what I've calculated here, which I have
     labeled absolutely clearly, is the percent of
9
10
     MMEs attributable to allegedly unlawful -- I
11
     say challenged -- unlawful promotion.
12
                   So that is illegitimate in a
13
     sense, in the sense that I understand
14
     plaintiffs' counsel intend to prove that the
     defendants' promotion from 1995 through 2018
15
16
     was unlawful.
17
     BY MR. METZ:
18
                   Okay. Let me ask it in a
            Ο.
19
     different way.
20
                   The information compiled in
21
     Table 2 could not be correctly characterized
22
     as having been compiled so that it would show
23
     an amount of opioid prescriptions that were
24
     dispensed based on prescriptions a pharmacist
25
     should have refused?
```

```
1
                   MR. SOBOL: Objection.
2.
     BY MR. METZ:
3
           Ο.
                   That's not the basis on which
4
     Table 2 is compiled, correct, as its author?
5
                   MR. SOBOL: Objection, asked
6
            and answered several times now.
7
                   I have not in my analysis
     analyzed the behavior of pharmacies or
8
9
     pharmacists, and so I cannot describe these
10
     data as reflecting the behavior of pharmacies
11
     or pharmacists.
12
                   Because of this issue around
13
     the causal chain that pharmacies, in fact,
14
     dispense prescriptions, I don't know if
     someone else would attribute this -- these
15
16
     same excess units to pharmacies. I haven't
17
     done that analysis.
18
                   I am not attributing these to
     pharmacists' behavior, but they are in the
19
20
     causal chain. So I'm saying I have described
21
     these as those units that are caused by the
22
     allegedly unlawful promotion. That's what
23
     they are.
24
                   Whether or not the pharmacists'
25
     or pharmacies' conduct is fully overlapping
```

- with the marketing manufacturers here, I
- don't know. I haven't been asked to look at
- 3 that question.
- 4 BY MR. METZ:
- 5 Q. In running the analyses that
- 6 resulted in the numbers in Table 2, it was
- never at any point your intention to compile
- 8 a table from which one would interpret that
- 9 as a volume of opioid prescriptions that were
- dispensed in excess of legitimate --
- 11 prescriptions that a pharmacist should have
- fulfilled after being presented with such
- prescriptions.
- MR. SOBOL: Objection, asked
- and answered, mischaracterizes prior
- testimony.
- 17 BY MR. METZ:
- 0. Isn't that correct?
- MR. SOBOL: Well, objection.
- Answer -- asked and answered,
- mischaracterizes prior testimony.
- If you want to give the same
- answer or whatever, go ahead.
- A. I'm not sure. In my analysis,
- I did not consider whether a pharmacist or

- 1 pharmacy should have done one thing or
- another. Again, they're in the causal chain.
- 3 They must have been involved in filling these
- 4 prescriptions, but I have not separately
- 5 analyzed the conduct of those pharmacists or
- 6 pharmacies; and moreover, when you use the
- 7 word "should," that sounds like there's
- 8 either a professional judgment or a legal
- ⁹ judgment, and I have not analyzed that kind
- of judgment.
- 11 BY MR. METZ:
- Q. Okay. I think I asked a
- complicated question, more so than I intended
- to be. Mine is just very simple.
- 15 As the person who compiled the
- information in that table, it was not done
- for the purpose of making the sort of claim
- that I just -- just stated in my previous
- question, correct? That was not the purpose
- of compiling the information in that table.
- MR. SOBOL: Objection, asked
- and answered.
- A. The purpose of Table 2 was to
- fulfill the part of my assignment where I was
- asked to quantify the impact of allegedly

- unlawful promotion on MMEs. That was the
- purpose of Table 2.
- 3 BY MR. METZ:
- Q. Okay. Now, you testified this
- 5 morning that you've not conducted any
- 6 analyses relating to suspicious order
- 7 monitoring for any defendant.
- 8 Do you recall that?
- 9 MR. SOBOL: Objection, asked
- and answered.
- 11 A. Yes.
- 12 BY MR. METZ:
- 13 Q. To take that one step further,
- you conducted no analysis seeking to identify
- any subset of your total MMEs increase that
- consists of opioid medications that were part
- of any order that plaintiffs or their experts
- have alleged to be suspicious. You've not
- conducted that analysis, correct?
- A. I have not conducted an
- 21 analysis of suspicious orders in -- within
- the context of my analysis and any suspicious
- order analysis.
- O. And as we discussed a few
- minutes ago, because your results are based

- on aggregate data for total MMEs, they do not
- contain the identifying information that
- would allow you to trace them back to
- 4 individual prescriptions, correct?
- 5 MR. SOBOL: Objection, asked
- and answered.
- 7 A. The data I have from the
- 8 National Prescription Audit do not have
- 9 identifiers, so in these data, I cannot trace
- them back to individuals.
- 11 BY MR. METZ:
- Q. Okay. And therefore, those
- 13 MMEs are also not traceable back to
- individual pharmacies, correct?
- MR. SOBOL: Objection, asked
- and answered.
- A. Again, in the aggregate data I
- have, that is correct.
- 19 BY MR. METZ:
- Q. And you've not attempted to
- trace them, correct?
- MR. SOBOL: Objection, asked
- and answered.
- A. I would have to get a different
- dataset for that.

- 1 BY MR. METZ:
- Q. Okay. And therefore, those
- MMEs are also not traceable back to
- 4 individual orders that pharmacies placed with
- their wholesale distributors, correct?
- 6 MR. SOBOL: Objection, asked
- and answered.
- A. My data are not at the right
- 9 level of disaggregation to track orders to or
- 10 from pharmacies.
- 11 BY MR. METZ:
- 12 O. And for that reason or other
- reasons, you've not attempted to make any
- such linkage, correct?
- MR. SOBOL: Objection, asked
- and answered.
- 17 A. I have not been asked to make
- any such linkage, and so, therefore, I have
- not acquired the data or undertaken that
- assignment.
- BY MR. METZ:
- O. And for that reason, if not
- others, would you agree with me that it would
- not be correct to characterize Table 2 as
- reflecting a percentage of MMEs distributed

```
as a result of suspicious orders?
1
2.
                   MR. SOBOL: Objection.
3
           Α.
                   These are -- oh, as a result of
4
     suspicious orders, sorry. It is -- these are
5
     a percentage of MMEs that were distributed as
6
               They reached patients at a pharmacy
     it were.
7
     as a result of promotional misconduct.
8
     have not analyzed suspicious orders. I do
9
     not know how those two things would
10
     intersect. These percentages reflect
11
     promotional impact.
12
                   MR. METZ: Thank you. Whoever
13
            is on the phone, if you would hit
14
           mute, please. We're hearing some
15
           background. Thank you.
16
     BY MR. METZ:
17
            Q.
                   Would you agree with me that as
18
     a general proposition, in a regression
19
     analysis, causality cannot be inferred by
20
     data analysis alone, rather, one must infer
21
     that the causal relationship exists on the
22
     basis of an underlying causal theory that
23
     explains the relationship between the two
     variables?
24
25
           Α.
                   It sounds like you're reading
```

- from a textbook. Generally, causation begins
- with an economic theory. I would agree with
- 3 the general premise of that statement.
- 4 Q. And would you also agree that
- 5 as a general proposition in regression
- analysis, even when an appropriate theory has
- been identified, causality can never be
- 8 inferred directly; one must also look for
- 9 empirical evidence that there is a causal
- 10 relationship?
- MR. SOBOL: Objection, asked
- and answered.
- 13 A. I would agree that in general,
- economists use both theory and empirical
- evidence to make causal inferences, yes.
- 16 BY MR. METZ:
- O. And consistent with those
- principles for your work in this matter, you
- have not posited a causal theory of how your
- calculation of the increase in total MMEs
- might be causally related to any alleged
- suspicious order by distributor defendants,
- 23 correct?
- A. I have not posited a theory
- related to suspicious orders. I have not

```
been asked to examine that question in any
1
2.
     way in my analysis.
3
                   And it follows you've also not
4
     looked for empirical evidence of any such
5
     causal relationship, correct?
6
                   MR. SOBOL: Objection, asked
7
            and answered.
8
                   Yes, I have not -- I have not
            Α.
     undertaken an analysis of suspicious orders.
10
     BY MR. METZ:
11
            Ο.
                   Okay. New topic.
12
                   In paragraph 56 of your report,
13
     you -- and I'm reading a truncated version of
14
     the quote, but, quote: While documents
15
     produced in discovery show many --
16
                   MR. SOBOL: Wait one second,
           please, if it's going to be truncated.
17
18
                   MR. METZ: Please.
19
            Α.
                   56? Yeah.
20
                   MR. SOBOL: Where are you?
21
                   THE WITNESS: At the bottom of
22
           page 38?
23
                   MR. METZ: I believe so.
24
                   THE WITNESS: Yes.
25
                   ///
```

- 1 BY MR. METZ:
- Q. You state: While documents
- produced in discovery show many examples of
- 4 such promotional efforts beyond detailing,
- for the purposes of my econometric analysis,
- 6 I rely on detailing contacts to measure
- 7 promotion for several reasons.
- 8 Do you see that?
- 9 A. I do.
- Q. Okay. Now, you testified about
- this yesterday, but I have a few follow-up
- questions.
- A. Sure.
- Q. As I understand your testimony
- and your report, one reason you rely upon
- detailing is that it's a form of marketing
- for which you have enough data to enable you
- to perform a time series regression; is that
- 19 correct?
- MR. SOBOL: Objection.
- 21 A. That is one of the reasons that
- I state in this paragraph, in addition and
- first and foremost, to it being a very
- important form of marketing, if not the
- dominant form of marketing.

```
1
     BY MR. METZ:
2.
                   Okay. So some of the other
            Ο.
3
     forms of marketing are not systematically
4
     tracked in data in the same way that the
5
     detailing is, correct?
6
            Α.
                   Yes, that's correct.
7
                   And you also believe, do you
            Q.
8
     not, that -- this is a quote: From an
9
     econometric standpoint, detailing is a good
10
     proxy for total promotional effort,
11
     including -- and closed quote -- including
12
     those other forms of marketing for which
13
     there's not systematic data, correct?
14
            Α.
                   Yes, that's correct.
15
                   All right. Now, in the
            Ο.
16
     following paragraph, paragraph 57, and then
17
     in Figure 5, you identify a series of what
18
     are labeled key events that would have
19
     affected the receptiveness of prescribers and
20
     patients to promotional messages about the
21
     safety and effectiveness of opioids.
22
                   Do you see that?
23
            Α.
                   I do.
24
                   Okay. And your understanding
25
     is plaintiffs allege that manufacturer
```

- defendants were responsible for those key
- 2 events?
- A. As you can see, looking at
- Figure 5, the events in red include many
- 5 policy/regulatory events, so the events in
- 6 green are ones that are described in
- 7 Dr. Perri's report, among other places.
- Q. Okay. So the answer to my
- 9 question would be yes, for the green-flagged
- 10 key events?
- 11 A. Yes.
- Q. How did you --
- MR. SOBOL: Or the answer she
- 14 gave.
- 15 BY MR. METZ:
- Q. How did you identify this list
- of key events?
- 18 A. The list comes from -- there's
- an FDA timeline that's available on their
- website that is included in my documents
- relied upon; the complaint, Dr. Perri's
- report. It's an aggregation of all those
- places.
- Q. Okay. Did you include every
- event that's listed in those sources?

- 1 A. No, I did not.
- O. With reference to the events
- flagged in green, what were your criteria for
- 4 inclusion from among the various events that
- were candidates based on those sources?
- 6 A. Sure. Again, as I said earlier
- yesterday, I believe, I sought to describe
- 8 some of the key events that were going on at
- 9 different stages of the analysis during the
- time frame, so I was looking to identify
- 11 events over time.
- In some cases there might be
- other events that coincide with these same
- events. I focused in terms of the events in
- green in particular ones that are highlighted
- in the complaint and in Dr. Perri's report.
- Q. Now, in your testimony
- yesterday, you were asked about one of these
- events. It was the consensus statement of
- the American Academy of Pain Management and
- the American Pain Society.
- 22 A. Yes.
- Q. Do you recall that?
- 24 A. I do.
- Q. And I want to ask a little

- follow-up about your testimony which, based
- on the rough transcript, was in part that
- that consensus statement related to the
- 4 undertreatment of pain and the need for more
- 5 attention to the treatment of pain and the
- 6 effective use of opioids for such treatment.
- 7 Do you recall that?
- A. Yes, that was my summary of it.
- 9 Q. And why would that make that
- 10 event significant?
- 11 A. I don't know what you mean by
- why would that summary make it significant.
- 13 Again, it's an event that's talked about in
- Dr. Perri's report and talked about in the
- 15 complaint.
- Q. This is a -- this is an event
- that, based on the information referred to in
- those places, you were hypothesizing could
- have had a causal relationship with the sales
- of MMEs, correct?
- A. That's right. I understand
- that Dr. Perri's opinion and plaintiffs
- intend to prove that these kinds of
- 24 professional society recommendations were
- manipulated by defendants.

- Q. Okay. And one of the reasons
- why that statement as you described it
- yesterday would be hypothesized to have a
- 4 causal influence is it referred to the notion
- 5 that there's an undertreatment of pain,
- 6 correct?
- 7 A. Yes.
- Q. And another of the reasons was
- because it referred to the notion that
- opioids could be effective treatment for such
- pain, correct?
- 12 A. That's correct.
- Q. Does the reputation of these
- two bodies play a role in its being
- considered a key event?
- A. Again, for my purposes, it's a
- notable event because it is featured in
- Dr. Perri's analysis and others, and I'm
- using Figure 5 to talk about particularly the
- 20 nonmarketing mechanisms that were allegedly
- 21 part of the overall effort to grow the market
- for opioids.
- So the reputation of the
- professional societies is likely a reason for
- which the marketing defendants allegedly

- influenced those -- that consensus statement
- and those guidelines because that is an
- ³ effective way of delivering their message.
- Q. Now, looking again at Figure 5,
- I see you have it in front of you, another of
- the key events that's flagged reads capital
- 7 V, cap A, "Pain as 5th Vital Sign."
- 8 Do you see that?
- 9 A. I do.
- 10 Q. Do you have an understanding of
- what that's referring to?
- 12 A. It was a VA statement, again,
- around the need to more closely monitor and
- 14 treat pain.
- Q. And the VA that you're
- referencing there is the U.S. Department of
- 17 Veteran Affairs?
- 18 A. It is.
- Q. And why would that be
- significant?
- A. Again, this is something that
- is described in Dr. Perri's report and is
- another example of the way defendants'
- message was legitimized through the
- activities of other stakeholder groups,

- including the VA.
- Q. Okay. And as you say
- "defendants" in that testimony, you mean
- 4 marketing defendants?
- 5 A. Yes, marketing defendants.
- 6 Q. Do you recall anything else
- about the VA's message other than it was
- 8 around a need to more closely monitor and
- 9 treat pain?
- 10 A. I don't recall all the details
- of it. I believe it's cited in my documents,
- so we could pull it up.
- Q. Okay. But it is, as you recall
- it, thematically consistent with the previous
- document in that it identified a need to have
- more expansive treatment of pain and
- identified opioids as one way of doing that?
- A. Yes. And I think what it
- became known for was this notion of the fifth
- vital sign.
- Q. That pain is the fifth vital
- 22 sign?
- A. That's correct.
- Q. Okay. And again, in the
- language we were referring to a few minutes

- before, you had a causal theory that a
- publication like that by an organization like
- the VA could have been causally related to
- 4 the sale of opioids, correct?
- 5 A. Yes. I believe that's what I
- describe in my report, that all of these
- 7 events collectively created an environment in
- 8 which physicians were more receptive to
- 9 pharmaceutical marketing.
- Q. And because it's flagged in
- green, the causal theory is that it would be
- positively correlated with sales, correct?
- 13 A. That was my causal theory, yes.
- Q. And so can we look at Table 1
- in your report, which is the --
- A. Regression results.
- Q. Well, it's the output from your
- direct regression.
- 19 A. Yes.
- MR. SOBOL: Do you have a page?
- MR. METZ: I do.
- THE WITNESS: 47.
- MR. SOBOL: Thank you.
- 24 BY MR. METZ:
- Q. And you testified about this

- 1 yesterday and over the course of today, and
- I'm just going to reference a couple of
- things to orient us and then I have some
- 4 follow-up questions.
- In your Model B, as you've
- 6 testified, you do not include a variable for
- 7 marketing conduct other than -- other than
- 8 detailing; isn't that correct?
- 9 A. The variable that I included in
- my model is detailing, the stock of
- detailing, yes.
- 12 Q. Okay. And your findings based
- on that model purport to explain more than
- 14 99% of the variation in total MMEs, correct?
- A. Based on this model, which also
- includes the price index, yes.
- Q. Okay. And that 99% is based on
- the R-squared statistic, correct?
- 19 A. Yes.
- Q. And then in your Model C, you
- include five additional dummy variables to
- test for whether specific events from your
- Figure 5 are having an influence on total
- MMEs, correct?
- A. That's correct.

- 1 Ο. And you talk about that a 2. little in paragraph 73 of your report? 3 Α. Yes. 4 Q. And in -- as you disclose 5 there, in your -- and as reflected, I think, 6 in Table 1, when you ran the model, including 7 those five dummy variables, you found that 8 two of them were statistically significant at the 5% level, correct? 9 10 That's correct. Α. 11 Ο. One is what you've titled the 12 1999 Federation of State Medical Boards Model 13 Guidelines dummy variable, correct? 14 Α. Yes. 15 And the other is the 16 rescheduling of hydrocodone, correct? 17 Α. That's correct. 18 Now, you've assigned names to
- 19 these dummy variables, but wouldn't you agree
- 20 that by definition, a dummy variable is not
- 21 actually testing for the influence of the
- 22 specific event described in its name?
- 23 MR. SOBOL: Objection.
- 24 Α. Well, I'm not sure I would
- 25 agree with that. They're intended to capture

- an event based on their timing. They are
- not -- they don't reflect a quantum, other
- than existence, and so hence, the name dummy
- 4 variable.
- 5 BY MR. METZ:
- Q. Okay.
- A. But they are still intended to
- 8 capture some kind of timing.
- 9 Q. They're intended to capture
- the -- an effect that's occurring with that
- time and an effect that may be correlated
- with the variable of interest, correct?
- 13 A. Yes, an effect on the variable
- of interest.
- Q. Okay. And so it's in contrast
- with, for example, your detailing data, which
- is populated by data that changes month to
- month. A dummy variable, especially as
- you've used it, has two settings, correct?
- A. A dummy variable, as anyone
- would use it, as it's defined, is either a
- one or a zero. They're very commonly used in
- regression analysis, as you may know.
- Q. I know.
- And so -- and you described

- this in paragraph 73. In your model you have
- a series of months where the dummy variable's
- yalue or the value of the data associated
- 4 with it is zero, correct?
- 5 A. That's correct.
- Q. And at a point in time that you
- determine for purposes of trying to capture
- 8 the effects of some event of interest, you
- 9 changed that value from zero to one, correct?
- 10 A. That's correct.
- 11 Q. And in your model you leave it
- turned on as it were --
- 13 A. Yes.
- Q. -- from then to the end of your
- data series, correct?
- A. True.
- Q. And that's not an automatic
- design feature one could turn a dummy
- variable on and off, correct?
- A. You can do whatever you like,
- of course, but for the most part, when we
- think about something that is released, that
- it's on and that it stays on. Unless, for
- example, there was a policy that was then
- reversed and then it would make sense to turn

```
    it off.
    Q. Right. So I understand that
    you selected the timing of these dummy
```

- 4 variables based on their proximity to the
- events after which they're named, correct?
- A. Yes.
- Q. But to be precise, regardless
- of the names, what they're capturing are
- 9 changes in the dependent variable, which in
- this case are the total MMEs, that are
- 11 correlated with influences existing at the
- time the dummy variable is turned on,
- 13 correct?
- MR. SOBOL: Objection, form.
- 15 A. Yes, they are capturing any
- shift that occurred around that time.
- 17 BY MR. METZ:
- Q. And if there are multiple
- events around that same time that are
- correlated with the explanatory variable in a
- similar way, the dummy variable will pick up
- their collective influence, correct?
- A. Yes. I believe I said the same
- thing when I explained why ultimately I do
- not use Model C.

- 1 Q. And you originally created
- Model C as a robustness test, correct?
- A. It is a check on Model B to
- 4 see, well, we had these events, if we picked
- 5 the ones that we think are important, do we
- 6 see any shift around that time period.
- So it's a check in that sense,
- and it seems to me based on the results that
- 9 it's not a sensible direction to go.
- Q. Well, maybe my question is
- meant to be -- I meant it to be a little bit
- simpler.
- 13 You designed Model C as a test
- of the robustness of Model B, rather than
- running that as a fully formed model. Isn't
- that what you say in your report?
- MR. SOBOL: Objection, asked
- and answered.
- 19 A. I describe it in that way as
- well, and in doing so, I look at Model C on
- its own merits as well.
- BY MR. METZ:
- Q. Okay. And the purpose -- so
- leaving aside your valuation of the merits of
- Model C on its own, I want to focus on the

- 1 robustness test purpose.
- The purpose of a robustness
- 3 test is to see the extent to which the
- 4 results of a regression model are sensitive
- 5 to changes in the underlying assumptions of
- 6 that model; is that correct?
- 7 A. Yes.
- Q. And you agree that robustness
- 9 is important to the validity of a regression
- model and its interpreted results?
- MR. SOBOL: Objection, form.
- 12 A. It's one way that we look at
- the validity of the model.
- 14 BY MR. METZ:
- Q. And so specifically here, to
- the extent your purpose was a robustness
- test, you were testing the assumption -- and
- 18 I'm quoting again from paragraph 73 -- the
- validity of the assumption that, quote,
- Model B implicitly accounts for non-detailing
- events and policies, closed quote, correct?
- 22 A. Yes.
- Q. And you tested that by
- examining whether indicators of specific
- events and policies should be explicitly

```
1
     included in the model, correct?
2.
            Α.
                   Yes.
3
                   Now, when you originally
4
     disclosed your report, you concluded that
5
     jointly all five events are not statistically
6
     different from zero, correct?
7
                   MR. SOBOL: Objection.
8
                   Yes, that was -- it was -- the
            Α.
9
     wrong test was referenced when the write-up
10
     was, although the right test was included in
11
     the results, but I was looking at the wrong
12
     test when I summarized that.
13
     BY MR. METZ:
14
            Ο.
                   Okay. And so just to hone in
15
     on the particular language that's used in
16
     your report, when you say jointly, all five
17
     events are not statistically different from
18
     zero, based on the discussion we had a minute
19
     ago, you mean the five dummy variables named
20
     after events as listed in Table 1 were not
21
     statistically different from zero as stated
22
     in your report originally?
23
                   MR. SOBOL: Objection.
24
           you want her to testify on the basis
25
            before the errata?
```

```
1
                   MR. METZ: I'd like her to
2.
            answer my question. But she's doing a
3
            fine job. If you don't understand my
4
            question, I'm happy to clarify.
5
           Α.
                   No, I think you just said
     something that would be -- I understand is
6
7
     accessible, but it would be a strange way to
8
     describe the results.
9
                   So I say that the dummies are
10
     or aren't significant, so I'm inferring from
11
     the dummy variables what I can learn about
12
     modeling those events in that on/off way.
13
     BY MR. METZ:
14
                   Well, if I -- if we took the
           Ο.
15
     sentence that's in your report that I quoted,
16
     the one beginning "jointly," and replaced the
17
     word "events" with "dummies," would it cease
18
     to be accurate?
19
           Α.
                   It would not. I'm just saying
20
     it would not be unusual for someone to
21
     describe their statistical results using
22
     dummy variables based on what the dummy
23
     variables are intended to represent.
                   Okay. And one of the reasons
24
25
     you've given for rejecting Model C was you
```

- found a counterintuitive result for your
- 2 hydrocodone event, correct?
- MR. SOBOL: Objection.
- 4 A. I gave that reason in addition
- 5 to the fact that it does not fundamentally
- 6 change my results.
- 7 BY MR. METZ:
- 8 Q. Okay. But that was one of your
- 9 reasons?
- 10 A. That's correct.
- Q. And because it's a dummy
- variable, that result may not be
- counterintuitive. It may be capturing an
- effect other than hydrocodone, correct?
- MR. SOBOL: Objection.
- A. Again, it's counterintuitive
- based on the event I put the dummy variable
- in to model, and like you, I wonder if it's
- capturing something else.
- BY MR. METZ:
- Q. Okay. It would be contrary to
- your expectations for why you put a dummy
- there in the first place and why you named it
- the way you did. But that doesn't rule out
- that it's accurately measuring some event

- that's actually going on at that place, just
- not one that you had hypothesized?
- MR. SOBOL: Objection, form,
- 4 asked and answered.
- 5 A. Yes, it is possible that it is
- 6 appropriately capturing something.
- 7 BY MR. METZ:
- Q. Okay. And that was one of two
- 9 events that you found that individually was
- statistically significant at the 5% level,
- 11 correct?
- 12 A. That's correct.
- Q. And you also, as you now
- disclosed in your errata, you also found that
- jointly, all five events are statistically
- different from zero, correct?
- 17 A. That's correct.
- Q. Okay. And returning to the
- 19 robustness test purpose of creating Model C
- in the first place, that shows, does it not,
- that your Model B is sensitive to some events
- outside the construct of Model B that are
- being captured by those dummy variables?
- MR. SOBOL: Objection.
- A. I would disagree. If you

- look -- if we go to look at the charts and
- you look at the extent to which my
- predictions changed, they hardly change at
- 4 all. The coefficients on the variables of
- interest, they hardly change at all.
- 6 BY MR. METZ:
- 7 Q. Well --
- A. The results are virtually the
- 9 same.
- 10 Q. Your coefficient for -- you
- have three time period coefficients for the
- detailing variable, correct?
- 13 A. That's correct.
- Q. And as you've discussed, you
- also construct the detailing variable
- differently in the different periods,
- 17 correct?
- 18 A. We discussed that. We can go
- over it again, but yes.
- Q. I'm just referencing that.
- A. Yes, let's reference that.
- Q. All right. The first time
- period detailing variable changes from
- Model B to Model C, does it not?
- A. It changes a small bit, but

```
1
     again, if you look at the predictions of
 2.
     actual versus but-for, the differences are
 3
     minute.
 4
            Q.
                   I'll get to that in a second.
 5
                   It changes, yes?
 6
                   MR. SOBOL: Well, no,
 7
            objection. She answered the question.
 8
                   MR. METZ: Fair enough.
 9
                   THE WITNESS: In my opinion --
10
     BY MR. METZ:
11
            Q.
                   I'll ask a different question.
12
            Α.
                   Okay.
13
                   Specifically, it changed by
            Ο.
14
     reporting a lower value in Model C for that
15
     coefficient as compared to Model B.
16
                   MR. SOBOL: Objection, asked
17
            and answered.
18
                   The coefficient is lower, yes.
            Α.
19
     BY MR. METZ:
20
                   And the interpretation of that
21
     is that in that Model C, when you include
22
     these dummy variables, some amount of the --
23
     what had previously been reported as the
24
     influence of the detailing is now being no
```

longer reported as the influence of the

25

- detailing, and it is being ascribed to one or
- 2 more of the dummy variables. Yes?
- MR. SOBOL: Objection.
- 4 A. There is some quantum. It is a
- 5 very small difference. In my view, given the
- 6 limitations of Model C and given the fact the
- 7 results are different by such a small amount,
- 8 Model B is preferred.
- 9 BY MR. METZ:
- Q. Okay. And you have a second
- period in which you report the detailing
- variable, and the coefficient on that
- variable also changes from Model B to
- 14 Model C, correct?
- 15 A. Yes, they do. The point
- estimates are different.
- Q. Okay. And they change in the
- same direction in that, again, the detailing
- is credited with less of an influence, and --
- A. I'd actually have to look.
- Q. -- some of that influence is
- credited instead to the dummy variables,
- 23 correct?
- A. There's -- you're right. There
- is a small decrease in the second coefficient

- and the third coefficient is the same.
- Q. Now, you've said many times
- that it is a small decrease, but a couple of
- 4 follow-ups about that.
- Is it standard practice in
- 6 econometrics to actually make qualitative
- ⁷ judgments about the differences between
- 8 coefficients based solely on their numeric
- 9 values?
- MR. SOBOL: Objection.
- 11 A. I do not include a conclusion
- about the quantitative difference between
- these coefficients. I explain my reasons for
- selecting Model B, and we've talked about
- them. In terms of the results of Model C,
- not based on the magnitude of that
- difference.
- 18 Had there been a larger
- magnitude of difference, I might have
- considered the challenges with Model C
- differently.
- BY MR. METZ:
- Q. I'm asking a simpler question,
- which is: To an econometrician, do the --
- what I'll call the real numbers -- so not

- their weighted or contextualized or --
- versions, but just the pure number, comparing
- 3 coefficients, coefficient A to coefficient B,
- 4 based solely on the number associated with
- 5 them, is that a comparison that
- 6 econometricians would typically make when
- 7 evaluating the significance of a change?
- 8 MR. SOBOL: Objection, asked
- 9 and answered, form.
- 10 A. I -- economists,
- econometricians, almost always make
- qualitative judgments about models because of
- course there's part of it that is based on
- theory as we've described.
- So might an econometrician make
- a quantitative analysis? Maybe. She might
- also make qualitative judgments about which
- model is preferred. Not everything can be
- described quantitatively.
- If I wanted to know exactly how
- different these models are, I could make that
- quantitative comparison. I was not
- 23 attempting to do that here.
- 24 BY MR. METZ:
- Q. I'm just referring back to

- where in response to my questions you kept
- 2 saying the difference was small.
- And so as further explanation
- on that, in comparing coefficients, don't you
- also need to know the scale against which
- 6 they're being measured?
- 7 MR. SOBOL: Objection, asked
- and answered.
- 9 BY MR. METZ:
- 10 Q. If you're comparing just the
- real numbers, you need to know the scale to
- which those correspond, correct?
- MR. SOBOL: Objection, asked
- and answered, mischaracterizes prior
- testimony.
- 16 A. Yes, and the scale is evident
- here, and again, if we go to the predicted
- values, the scale is evident there as well.
- 19 BY MR. METZ:
- Q. Did you not testify repeatedly
- yesterday that the reason it doesn't matter
- that you have an inflationary depreciation
- rate is because all that that does is it gets
- caught up in muting the impact of the
- coefficients on the particular variables at

```
the particular times that they're measured?
1
2.
                   MR. SOBOL: Objection, asked
3
            and answered.
4
     BY MR. METZ:
5
                   Didn't you testify to that?
           Ο.
6
                   MR. SOBOL: Objection, form,
7
            asked and answered.
8
                   I don't believe that I stated
           Α.
     that in the way that you have. All I said is
9
10
     that the fact that promotional stock inflates
11
     doesn't necessarily mean that the effect has
12
     to inflate in the same way because the
13
     measured promotional effectiveness, as we see
14
     in both of these models, I find it decreasing
15
     over time, and that counteracts.
16
                   I didn't say it doesn't -- it
17
     doesn't have any effect. I'm just saying
18
     that the effect of the misconduct is a
19
     function both of the magnitude of the stock
20
     and of the promotional effectiveness.
21
     BY MR. METZ:
22
                   And also in reference to your
23
     answers to me that these changes don't matter
24
     because the effect was small, it's also the
25
     case that those changes, as you characterized
```

```
1
     as small, are the result of five dummy
2.
     variables you included as a singular
3
     robustness test, not a comprehensively
     designed model attempting to comprehensively
5
     control for these kinds of external events,
6
     correct?
7
                   MR. SOBOL: Objection, form,
8
            asked and answered, mischaracterizes
9
           prior testimony.
10
                   As I described yesterday, and I
11
     would restate now, given the performance of
12
     these selected dummy variables, given the
13
     adjusted R-squared of the model, the notion
14
     that adding all of the events would improve
15
     the performance of the model makes little
16
     sense to me. And that is why I did not run a
17
     model with every dummy variable in it.
18
     BY MR. METZ:
19
                   Well, after running a model
20
     with dummy variables, two of which
21
     individually were statistically significant,
22
     and the five of which were collectively
23
     statistically significant, you did not
```

attempt to construct a further model with

more dummy variables to see whether or not

24

25

- that had a greater impact on your measure of
- the relationship between detailing and MMEs,
- ³ did you?
- 4 MR. SOBOL: Objection.
- 5 A. Having run Model C and
- 6 comparing the results to Model B, I deemed
- 7 that it would not be fruitful to add further
- 8 dummy variables and run a more expansive
- 9 version of Model C.
- 10 BY MR. METZ:
- 11 Q. Do you agree that as a general
- matter in regression analysis failure to
- include a major explanatory variable that is
- correlated with the variable of interest in
- the regression model may cause an included
- variable to be credited within an effect that
- actually is caused by the excluded variable?
- A. As we discussed earlier today,
- that notion which you just describe of
- omitted variable bias is a factor in any
- 21 analysis, and there are constraints on how
- many variables one can include in an
- ²³ analysis.
- So while it's always going to
- be true that there is a possibility of

- omitted variable bias, it's my opinion that
- including more of these event variables in
- the model would not improve the performance
- 4 of the model.
- 5 O. You mentioned the word
- 6 "constraint" in that answer. And in previous
- 7 testimony you've mentioned a term called
- 8 "degrees of freedom."
- 9 A. Yes.
- Q. Can you explain what degrees of
- 11 freedom are as related to a constraint on the
- 12 number of variables that can be included in a
- model?
- 14 A. It has to do with the number of
- observations and the number of included
- variables. It also has to do with the
- correlation in these data, so as we add more
- and more dummy variables, the chances that we
- get colinearity are higher.
- Q. And degree of freedom refers in
- part to a point beyond which there's
- insufficient data to account for the number
- of permutations that more and more variables
- will introduce into the model; is that fair?
- A. In effect, it makes it

```
impossible to estimate the model.
```

- Q. Okay. Did you have adequate
- data to add additional dummy variables beyond
- 4 the five you included without running into
- 5 the limit imposed by however many degrees of
- 6 freedom you had?
- 7 MR. SOBOL: Objection, assumes
- 8 a fact not in evidence.
- 9 A. I have adequate data in terms
- of degrees of freedom. In terms of concerns
- about adding more dummy variables and having
- them be correlated with one another to the
- point where I'm getting results like the ones
- 14 I can see in Model C, where the coefficients
- are clearly picking up something different,
- that is the concern.
- BY MR. METZ:
- 18 Q. So if I understand, your
- concern is that had you inquired further, you
- might have found nonsensical results?
- MR. SOBOL: Objection,
- mischaracterizes the testimony.
- A. My concern is that adding dummy
- variables would likely just make the other
- dummy variables nonsensical, whereas Model B

- compared to Model C, again, has qualitatively
- 2 similar promotional effects that adding
- further dummy variables would simply
- 4 interfere with the meaning of the dummy
- 5 variables that are already in them. They
- 6 would be impossible to differentiate.
- 7 BY MR. METZ:
- Q. What's the basis for your
- 9 statement that would likely be the
- 10 consequence of adding additional dummy
- 11 variables?
- 12 A. Just we talked before that
- these dummy variables are zero until they
- turn on and one after, and if we add one
- every six months, then we have a whole lot of
- vectors that are zero. You know, sort of in
- a staggered way, they're going to be highly
- 18 correlated.
- 19 Q. And nonetheless, you did not
- test whether that would be the outcome of
- 21 adding additional dummy variables or other
- explanatory variables, correct?
- A. I did not consider adding other
- dummy variables.
- Q. Okay. And there are

- 1 conceivably other variables that are not
- dummy variables that one could add to test
- for the presence of additional factors,
- 4 correct?
- MR. SOBOL: Objection.
- A. I include the standard factors
- 7 that are included in an aggregate time series
- 8 analysis of pharmaceutical promotion, which
- 9 are -- I'm sorry, of pharmaceutical sales,
- which are promotion and price.
- 11 BY MR. METZ:
- Q. Okay. But there are -- in any
- regression, one of the tasks is to
- hypothesize as to other conduct that could
- affect the variable of interest, and where
- available, to include data that would capture
- that conduct, correct?
- MR. SOBOL: Objection, asked
- and answered.
- 20 A. Starting with the theory of
- demand for pharmaceuticals, I've constructed
- this model, including the most important
- variables, and again, one does not -- a
- well-constructed model focuses on the most
- 25 important variables.

```
1
                   This model using price and
2.
     promotion is the same as models that I have
3
     used in similar instances, and it's very
4
     similar to the models in Berndt, except that
5
     those are at product level, but they also
6
     focus on price and promotion.
7
                   So in a time series context,
8
     there aren't a lot of other variables that
     you could even imagine would be included, and
10
     in my opinion, price and promotion are the
11
     key variables here.
12
     BY MR. METZ:
13
                   Did you spend any significant
14
     time in contemplative thought trying to
15
     imagine additional variables to include in
16
     your model beyond the ones you included?
17
                   MR. SOBOL: Objection, asked
18
            and answered.
19
            Α.
                   I've spent 300 hours in
20
     developing the analyses that are in my
21
               I spent considerable time thinking
22
     about this model, and it wasn't the first
23
     time that I had thought about such analyses,
24
     as you know.
25
                   ///
```

- 1 BY MR. METZ:
- Q. Now, did you -- within those
- 3 300 hours, did you spend any significant time
- 4 seeking to identify the key events that
- 5 should be attempted to be replicated with the
- dummy variables you ended up using?
- 7 MR. SOBOL: Objection, asked
- 8 and answered.
- 9 A. Yes, you can see in my report
- that I culled those events again from various
- sources.
- 12 BY MR. METZ:
- 13 Q. Yes, and when I asked you about
- it, the answer you gave to me was that you
- looked at the expert report of Dr. Perri.
- A. Yes.
- Q. You looked at the plaintiffs'
- complaint.
- 19 A. Yes.
- Q. And you looked at one timeline
- on the website, I believe of the FDA?
- A. The FDA timeline. Those are
- the primary sources, yes.
- Q. Okay. Now, did you see
- Dr. Perri's report significantly before your

```
own report was finalized?
```

- A. I don't know what you mean by
- 3 significantly.
- 4 Q. Well, in time to adequately
- 5 evaluate whether the events described there
- 6 were the key events you should be attempting
- 7 to model for?
- 8 A. Yes, I did.
- 9 Q. How many days in advance?
- MR. SOBOL: Objection.
- 11 A. I can't say. I can't say for
- sure when I saw that, but I obtained the
- information from Dr. Perri's report as I was
- 14 putting together my model.
- 15 BY MR. METZ:
- Q. Okay. Was it time adequate
- that when you ran your Model C and two of the
- dummy variables came back individually
- significant and the five collectively came
- back significant, did you then have time to
- 21 consider and design and implement and still
- disclose on time another model with better
- dummy variables?
- 24 A. The --
- MR. SOBOL: Objection to

```
"better."
 1
 2.
                   Time was not the issue here.
 3
     decided not to run a model with more dummy
 4
     variables.
 5
     BY MR. METZ:
 6
            Ο.
                   Okay. I'm going to hand you
 7
     what we're marking as Exhibit 29.
 8
                    (Whereupon, Deposition Exhibit
 9
            Rosenthal-29, Joint Statement,
10
            Promoting Pain Relief and Preventing
11
            Abuse of Pain Medications: A Critical
12
            Balancing Act, was marked for
13
            identification.)
14
     BY MR. METZ:
15
                   Have you seen Exhibit 29
            Ο.
16
     previously?
17
            Α.
                   I believe so, yes.
18
                   What is it?
            Ο.
19
            Α.
                   I'm actually looking for the
20
     date on it. Does it have a date?
21
                   Well, I can represent to you
22
     that the particular version you're holding
23
     was pulled from an Internet archive that
24
     dates it as of a date that it was on the
25
     Internet, which may not be the first date it
```

- was on the Internet.
- A. I see.
- Q. And in the top right corner it
- dates it as November 27, 2001.
- 5 A. I think is the -- it's the
- 6 joint statement on promoting pain relief and
- 7 preventing abuse of pain medications, but,
- 8 sorry, what date did you think it was
- 9 actually from?
- 10 Q. Well, the date that this
- 11 particular copy is from --
- 12 A. Right.
- 13 Q. -- is November of 2001.
- 14 A. So it came out sometime before
- 15 that.
- 16 Q. The date it was pulled on the
- 17 Internet. I can't represent to you what date
- exactly it was, although I believe it to be a
- somewhat consistent time to what's reflected
- here, but I can't represent that to you.
- A. Yes, I'm not sure if I have
- seen this specific document.
- Q. Okay. And do you believe in
- looking at your Figure 5 that this is one of
- the event -- the key events dated on your

timeline? 1 2. Α. I'd have to look. 3 MR. SOBOL: Objection. 4 Α. I just need to go back and 5 find --6 BY MR. METZ: 7 Ο. I think Figure 5 is on page 41. 8 Α. Thank you. I must have blown 9 past it. 10 I don't believe that this is 11 part of it. I was thinking of the consensus 12 statement. But I think this joint statement 13 is something different, but --14 Ο. Okay. 15 It's certainly labeled Α. 16 something different. 17 Q. So to your knowledge, you have 18 not seen this previously; is that correct? 19 Α. To my knowledge, no. 20 All right. It's titled A Joint Q. 21 Statement from 21 Health Organizations and 22 the Drug Enforcement Administration. 23 Do you see that? 24 I do. Α. 25 And the title beneath that is Q.

```
1
     Promoting Pain Relief and Preventing Abuse of
 2.
     Pain Medications: A Critical Balancing Act.
 3
                   Do you see that?
 4
            Α.
                   I do.
 5
                   Okay. And since you've not
            Ο.
 6
     seen this before, I just want to read some of
 7
     the included terms.
                           It begins:
 8
     representatives of the healthcare community
 9
     and law enforcement, we're working together
10
     to prevent abuse of prescription pain
11
     medications while ensuring that they remain
12
     available for patients in need.
13
                   Do you see that?
14
            Α.
                   Yes.
15
                   And then skipping over a
16
     paragraph, the next one down, it says:
17
     Preventing drug abuse is an important
18
     societal goal, but there is consensus by law
19
     enforcement agencies, healthcare
20
     practitioners and patient advocates alike
21
     that it should not hinder patients' ability
22
     to receive the care they need and deserve.
23
                   Do you see that?
24
                   I do.
            Α.
25
                   And then it says:
                                       This
            Q.
```

```
1
     consensus statement is necessary based on the
2.
     following facts.
3
                   First bullet: Undertreatment
4
     of pain is a serious problem in the United
5
     States, including pain among patients with
6
     chronic conditions and those who are
7
     critically ill or near death. Effective pain
8
     management is an integral and important
     aspect of quality medical care and pain
9
10
     should be treated aggressively.
11
                   Do you see that?
12
            Α.
                   I do.
13
                   And then the next bullet says:
            Ο.
14
     For many patients, opioid analgesics, when
15
     used as recommended by established pain
16
     management quidelines, are the most effective
17
     way to treat their pain and often the only
18
     treatment option that provides significant
19
     relief.
20
                   Do you see that?
21
            Α.
                   I do.
22
                   And would you agree with me
            Ο.
23
     that shares some of the characteristics of
24
     the statement you testified about earlier as
25
     well as yesterday, the joint statement?
```

```
1
                   MR. SOBOL: Objection, beyond
2.
            the scope.
3
           Α.
                   Are you referring to --
4
                   MR. METZ: Beyond the scope of
5
           what?
6
                   MR. SOBOL: Beyond the scope of
7
           her opinions. You've got a document.
8
                              That's the point.
                   MR. METZ:
9
                   MR. SOBOL: You've got a
10
            document before her that she says she
11
           hasn't seen before.
12
                   MR. METZ: Okay. Thank you.
13
                   MR. SOBOL: And you're asking
14
           her then to, so far, just read it with
15
           you, and now you've asked her to
16
            compare a document that she hasn't
17
            seen to a document that is referenced
18
            in her report, right? So that's
19
           beyond the scope of her opinion.
20
     BY MR. METZ:
21
                   Would you agree with me that
22
     this document and the portions I just read in
23
     particular share some of the characteristics
24
     that you identified about the joint statement
25
     that you testified about earlier today in
```

```
1
     answer to my questions as well as yesterday?
2.
                   MR. SOBOL: Objection, form and
3
            beyond the scope.
4
                   Yesterday and today we talked
5
     about the American Academy of Pain Management
6
     and American Pain Society consensus
7
     statement, and how it describes pain as being
8
     undertreated and the utility of opioid
9
     treatment.
10
                   So in that sense, I can read
11
     here that this statement also describes pain
12
     as undertreated and opioid analgesics as an
13
     effective treatment.
14
     BY MR. METZ:
15
                   And we discussed as well the --
            Ο.
16
     at least the potential that the reputations
17
     of the bodies making those statements would
18
     be part of what made that -- a statement like
19
     that significant.
20
                   Do you recall discussing that
21
     with me?
22
                   MR. SOBOL: Objection. Is the
23
            question -- no --
24
                   MR. METZ: The question is if
25
            she recalls the testimony.
```

```
1
                   MR. SOBOL: Okay. So
           objection, mischaracterizes her prior
3
           testimony, and form.
4
                   I recall the discussion where I
5
     said that I believed one of the reasons that
6
     pharmaceutical manufacturers might seek to
7
     influence such statements is because the
     reputation of professional societies may
8
     legitimize their activity.
10
     BY MR. METZ:
11
           Ο.
                   Okay. And you would agree with
12
     that the -- as a general matter, the Drug
13
     Enforcement Administration is a reputable
14
     organization on matters pertaining to the
15
     legitimate use of controlled substances?
16
                   MR. SOBOL: Objection, scope of
           her opinion.
17
18
                   I understand that the Drug
           Α.
     Enforcement Administration is the federal
19
20
     agency responsible for enforcing laws that
21
     pertain to controlled substances. I don't
22
     know -- I quess I don't know "reputable."
23
     I'm not an expert on the DEA. I don't really
     know its reputation. I certainly know what
24
25
     its function is.
```

```
BY MR. METZ:
1
                   You think the DEA might be
2.
3
     disreputable on the subject of legitimate
4
     uses of controlled substances?
5
                   MR. SOBOL: Objection, scope,
6
            form.
7
                   I'm just saying I don't know
8
     the DEA's reputation. I know its purpose is
     to regulate controlled substances.
10
     BY MR. METZ:
11
                   As an economist forming
            Ο.
12
     hypotheses --
13
                   MR. SOBOL: Wait a second. Are
14
            you done with this exhibit?
15
                   MR. METZ: I haven't marked a
16
            new one. Is there a reason for
17
            interrupting me?
18
                   MR. SOBOL: Yes. I want to
19
            know if you were done with this
20
            exhibit.
21
                   MR. METZ: For what purpose?
22
            If you want -- I've set mine aside.
23
            If you'd like to set yours aside, set
24
            it aside, but I don't see the purpose
25
            for interrupting me.
```

```
1
                   MR. SOBOL: Okay. You've asked
2.
            to set it aside. I move to strike all
3
            the questions regarding the exhibit
4
           because they do not relate to the
5
            report and she has not seen the
6
            exhibit before.
7
                   MR. METZ: Well --
8
                   MR. SOBOL: Go ahead.
9
                   MR. METZ: -- that's the point
10
            in cross-examining an expert on the
11
            sufficiency of her inquiry is to test
12
           her on things that she might not have
13
            inquired about or seen, perhaps
14
           because Dr. Perri didn't flag them for
15
           her.
16
     BY MR. METZ:
17
                   The question I was going to ask
18
     you is: An economist, hypothesizing the key
19
     events that might be causally related to the
20
     sale of MMEs, and bearing in mind that you
21
     previously said a statement like this from a
22
     private organization would be sufficient to
23
     at least form a hypothesis, would you not
24
     hypothesize that the DEA among 28 other
25
     health organizations recognizing the
```

```
1
     undertreatment of pain and the potential for
2
     opioids to treat, not just pain generally but
3
     also chronic pain, could potentially have had
4
     an impact on MME sales?
5
                   MR. SOBOL: Objection.
6
     BY MR. METZ:
7
                   Is that a reasonable hypothesis
            Ο.
8
     for an economist in your position undertaking
9
     a study like this?
                   MR. SOBOL: Objection, form,
10
11
            compound.
12
                   A statement like this, like the
            Α.
13
     statements I do cite in my report, may have
14
     had an effect on sales, and because there
15
     were many such statements happening, I use
16
     the differential promotional effectiveness
17
     over time to capture these broader effects
18
     across a larger number of factors.
19
                   I believe something like this,
20
     if it were widely disseminated -- I don't
21
     really know how widely disseminated this
22
     was -- may have had an effect, and therefore,
23
     that would be captured in my promotional
     effectiveness.
24
25
                   ///
```

```
1
     BY MR. METZ:
 2.
                   Well, that's the hypothesis
            Ο.
 3
     described in paragraph 73 that Model C was
 4
     intended to test, correct?
 5
                   MR. SOBOL: Objection,
 6
            misrepresent -- mischaracterizes the
 7
            testimony.
 8
                   My hypothesis is that these
            Α.
 9
     events early and late affected promotional
10
     effectiveness. Model C is a particular way
11
     of testing them, which has the limitations of
12
     involving a large number of dummy variables.
13
                   I conclude that those dummy
14
     variables do not qualitatively affect my
15
     results, and we can go back to that
16
     discussion if you want, but that was my
17
     conclusion.
18
     BY MR. METZ:
19
            O.
                   Yeah.
20
                   And that, in fact, the
            Α.
21
     differential promotional effectiveness over
22
     time is picking up the influence of these
23
     environmental factors.
24
                   Okay. Only because I'm short
```

on time I'll ask it this way.

25

```
1
                   You described in paragraph 73
 2.
     of your report a hypothesis about the need to
 3
     explicitly include control for these kinds of
 4
     events as being the purpose of the robustness
 5
     test in paragraph 73.
 6
                   That's what you -- or the
 7
     robustness test in Model C, excuse me.
 8
     That's what you say in paragraph 73, correct?
 9
                   MR. SOBOL: Objection.
10
            Objection to the form.
11
            Α.
                   In paragraph 73, I say, in the
12
     middle of the first sentence: I tested the
13
     robustness of Model B by examining whether
14
     indicators of specific events and policies
15
     should be explicitly included in my model.
16
     BY MR. METZ:
17
            Ο.
                   Thank you.
18
                   And in Model C, where you
19
     included dummy variables, you included three
20
     dummy variables that turned on --
21
            Α.
                   Yes.
22
                   -- prior to -- prior to
            Ο.
23
     November of 2001, correct?
24
                   That's correct.
            Α.
25
            Q.
                   And the most proximate in time
```

- of those turned on -- was it in January of
- 2 2001 or does it turn on in February? I
- wasn't clear from the way you described in
- 4 your model.
- 5 A. I need to look in the errata,
- 6 because I think what was stated in the report
- 7 was different in two different places.
- Q. Okay.
- 9 A. So let me just take a quick
- 10 look.
- Q. For purposes of my question
- this will be sufficient.
- 13 A. Okay.
- Q. It's either/or January or
- 15 February, correct? If the dummy variable is
- dated January 2001.
- 17 A. I believe that that is true. I
- just didn't want to misstate it. You're
- talking about the JCAHO pain standards.
- 20 Q. Yes.
- A. Yes.
- Q. Okay. And then if this
- statement, in fact, was released in November
- of 2001, that is ten months after your dummy
- variable had already turned on, correct?

- 1 A. That's correct.
- Q. And then you do not have
- another dummy variable that you include until
- 4 August of 2010, which is close to nine years
- 5 later.
- A. Yes. And because the dummy
- 7 variable stays on, it will pick up any level
- 8 shift over time after that, controlling for
- 9 other factors, right.
- Q. Any level shift that in the
- calculation shows up is correlated with the
- dummy variable from nine months earlier,
- 13 correct?
- 14 A. Yes, but again, the dummy
- variable stays on over the period when this
- would have been released.
- 0. Does not the distance from the
- dummy variable have a bearing upon the
- significance that that variable will attach
- to events later in time?
- A. Well, again, it is literally
- picking up an average shift before compared
- to after.
- O. Okay. And if there are other
- unexplained events going on, you might

- attribute those to dummy variables that are
- years apart from when you first turned them
- on, correct?
- 4 MR. SOBOL: Objection.
- 5 A. This is why I conclude that
- 6 Model B is the more appropriate approach
- ⁷ here, to not try to disentangle those things.
- 8 BY MR. METZ:
- 9 Q. Okay. But in the ideal design
- of your model, as you told me before, you
- picked the timing of the dummy variable to
- coincide with the key events, not to have
- them be months prior so that they'll just
- sweep them up eventually, correct?
- MR. SOBOL: Objection, form.
- 16 A. The dummy variables are
- intended to reflect the timing of these key
- events? Yes.
- 19 BY MR. METZ:
- Q. The -- any dummy variable, the
- timing for when you turn it on, is intended
- to be timing that makes sense in light of the
- key events you're testing for, right?
- A. It does. I'm just saying that
- just mathematically, the case that while that

```
timing is important, it's important because
1
2.
     it differentiates pre from post.
3
     doesn't -- it's not instantaneous.
4
                   Okay. And nonetheless, you put
5
     your variable in January 2001 in order to
6
     attempt to simulate for an event occurring in
7
     or around January 2001, correct?
8
                   MR. SOBOL: Objection, asked
9
            and answered.
10
            Α.
                   Yes.
11
                   (Whereupon, Deposition Exhibit
12
            Rosenthal-30, State of Ohio House Bill
13
            No. 187, was marked for
14
            identification.)
15
     BY MR. METZ:
16
                   I'm going to hand you an
17
     exhibit we've marked Exhibit 30. I'd like
18
     you to take a look at that and tell me if
19
     you've seen it before.
20
                   I just want to check my
     documents relied upon. My memory is not
21
22
     always reliable.
23
                   (Document review.)
24
                   I don't think that I've seen
            Α.
25
     this document before.
```

- 1 BY MR. METZ:
- Q. Well, in that case, Exhibit 30
- is a printout from a legal -- well, from a
- 4 book of Ohio session laws, and it's entitled
- 5 H.B. No. 187, and in the title it says
- 6 Treatment of Intractable Pain.
- 7 Do you see that?
- 8 A. I do see that.
- 9 Q. Okay. It's described as an act
- regarding the authority of physicians to
- prescribe, dispense and administer dangerous
- drugs for management of intractable pain.
- Do you see that?
- 14 A. I see that.
- Q. And under the first -- when you
- look into the body of the bill, next to
- number 2 it defines intractable pain.
- Do you see that?
- A. Yes.
- Q. And it means a state of pain
- that is determined, after reasonable medical
- efforts have been made to relieve the pain or
- cure its cause, to have a cause for which no
- treatment or cure is possible or for which
- none has been found.

```
1
                   Do you see that?
 2.
            Α.
                   Yes.
 3
                   And then if you skip down
            Q.
 4
     to (C), the bill states that when a physician
 5
     diagnoses an individual as having intractable
 6
     pain, the physician may treat the pain by
 7
     managing it with dangerous drugs in amounts
 8
     or combinations that may not be appropriate
 9
     when treating other medical conditions.
10
                   Do you see that?
11
            Α.
                   I do.
12
                   Do you understand intractable
            Q.
13
     pain as so described here to have a similar
14
     meaning to chronic pain?
15
                   MR. SOBOL: Objection, scope.
16
                   I do not, no.
            Α.
17
     BY MR. METZ:
18
            Ο.
                   Okay. Do you understand it to
19
     be describing pain for which -- pain that
20
     will endure over a longer period because
21
     there is no -- no other means of curing it?
22
                   MR. SOBOL: Objection, scope.
23
            Α.
                   Well, I'm not a clinical
24
               It seems to define it as having no
25
     treatment or cure.
                          It does not say anything
```

- about the longevity of the pain.
- 2 BY MR. METZ:
- Q. Okay. And then if you flip
- 4 ahead to subpart (D), which is on the second
- 5 page, it states that a physician who treats
- 6 intractable pain by managing it with
- dangerous drugs is not subject to
- 8 disciplinary action by the board under
- 9 Section 4731.22 of the revised code, solely
- because the physician treated the intractable
- pain with dangerous drugs.
- The physician is subject to
- disciplinary action only if the dangerous
- drugs are not prescribed, administered or
- dispensed in accordance with this section and
- the rules adopted under it.
- Do you see that?
- 18 A. I do.
- Q. And were you aware prior to
- this moment of a law that was passed in Ohio
- in the late 1990s that provided doctors with
- legal protection for -- against circumstances
- in which they treated patients with pain
- using dangerous drugs? Were you aware of
- such a law being passed?

```
1
                   MR. SOBOL: Objection, form.
2.
                   I couldn't have told you when
           Α.
3
     such a law was passed in Ohio.
4
                   I was aware from the complaint
5
     and from Dr. Perri's report that the
6
     influence -- the industry allegedly
7
     influenced such quidelines, including, as I
8
     include in my timeline, the model guidelines
9
     supplied by the Federation of State Medical
10
     Boards, and I take this to be an example of
11
     one that was implemented in Ohio.
12
     BY MR. METZ:
13
                   So is it your understanding
14
     that a state medical board quideline and a
15
     Ohio statute passed by the legislature of
16
     Ohio to be functionally equivalent? Is that
17
     what your answer was?
18
                   MR. SOBOL: Objection,
19
           mischaracterizes her testimony.
20
                   MR. METZ:
                              That's why I'm
21
            asking for clarification.
22
                   I'm not a lawyer or a state
           Α.
23
     regulatory expert. These guidelines that I'm
24
     seeing for the first time reading them, they
25
     are consistent with what I understand the
```

- qoal of the Federation for State Medical
- Board Model Guidelines were, this protection
- ³ from liability.
- 4 BY MR. METZ:
- 5 Q. They're consistent in their
- 6 goals; they're inconsistent that -- in the
- ⁷ sense that in this instance, pertaining to
- Ohio, it's being adopted by the 122nd Elected
- 9 General Assembly of the State of Ohio.
- Do you see that?
- MR. SOBOL: Objection. Oh,
- just do you see that? That's fine.
- 13 A. I do.
- 14 BY MR. METZ:
- Q. Okay. And do you agree with me
- that there is a difference between a private
- or a standard-setting unelected body creating
- some rule or regulation and the elected
- assembly of a state like Ohio enacting a law?
- MR. SOBOL: Objection to the
- scope.
- BY MR. METZ:
- Q. Do you see a difference between
- those two things?
- MR. SOBOL: Objection to scope.

- 1 A. I'm not a legal or regulatory
- expert, so I don't have an opinion about the
- different effects of those two things.
- 4 BY MR. METZ:
- Okay. To be clear, I wasn't
- 6 asking about effects. I was asking about the
- 7 nature of the body adopting them.
- 8 Do you see a difference in the
- 9 nature of the body adopting what you've
- described as guidelines versus the Assembly
- of Ohio adopting a law?
- MR. SOBOL: Objection, asked
- and answered.
- 14 A. I understand that -- again, I
- understand that this is a law, and I believe
- the model guidelines were intended to
- influence regulations. I understand the
- difference between those two things.
- 19 BY MR. METZ:
- Q. Okay. Thank you.
- Now, this also does not appear
- on your timeline of key events, correct?
- A. It does not.
- Q. Okay. And you did not design a
- dummy variable with the specific intention of

```
trying to capture any effects from this law,
```

- 2 correct?
- A. I did not.
- Q. Okay. And, in fact, although
- 5 your testimony is being used solely for
- 6 purposes of this case, within two counties in
- Ohio, your aggregate analysis is done on a
- 8 national level, correct?
- 9 MR. SOBOL: Objection, asked
- and answered.
- 11 A. My analysis is a national
- 12 aggregate analysis.
- 13 BY MR. METZ:
- Q. And one consequence of doing a
- national aggregate analysis is that if a law
- like this had an impact within the state of
- Ohio, that effect might be muted in your
- national analysis because there's 49 other
- states, right?
- MR. SOBOL: Objection, form.
- A. The national analysis will be
- 22 affected by the extent of such laws across
- the country, not on just one state.
- 24 BY MR. METZ:
- O. And if Ohio was

- disproportionately affected by a law such as
- this, that effect might be different from the
- 3 average that's reflected in your national
- 4 aggregate analysis, correct?
- MR. SOBOL: Objection, form.
- A. That may be the case. As I
- 7 understand this law, it seems to be that it
- 8 would cause even more prescribing than I
- 9 estimate on average, if other states lag
- 10 Ohio.
- 11 BY MR. METZ:
- 12 Q. Okay. Even more within Ohio is
- what you're saying?
- 14 A. Even more than I attribute to
- Ohio, yes.
- Okay. Now, that law was not
- identified for you by Dr. Perri as one of the
- key events as it related to your opinions for
- 19 Cuyahoga and Summit Counties, correct?
- A. Just to be clear, Dr. Perri
- wasn't identifying for me. I understand the
- events that he described in his reports, that
- he identifies as part of his report as being
- important.
- Q. And in part because this was

- not described in that report and because it is not reflected in plaintiffs' complaint,
- it's not one of the key events that you put
- 4 into your Figure 5, correct?
- MR. SOBOL: Objection,
- 6 mischaracterizes the testimony.
- 7 A. I do not believe it appears in
- 8 the sources that I used to put together
- 9 Figure 5.
- 10 BY MR. METZ:
- 11 Q. Okay.
- 12 A. So I did not rely on it.
- Q. In the inquiry you
- independently undertook to identify what key
- events should be accounted for in your model,
- did you come across any information
- indicating that, in fact, this law had had an
- influence on MMEs within the state of Ohio
- such that it should be accounted for?
- A. I am not aware of anything, no.
- I did not come across that.
- 22 (Whereupon, Deposition Exhibit
- Rosenthal-31, Ohio Prescription Drug
- Abuse Task Force Final Report, was
- marked for identification.)

```
BY MR. METZ:
1
           Q. I'm going to hand you an
     exhibit marked Exhibit 31.
3
                  MR. SOBOL: Where are we on the
5
           time?
6
                  MR. METZ: I think I have about
7
           15 minutes.
8
                  THE VIDEOGRAPHER: 19.
9
                  MR. SOBOL: Thanks.
10
                  THE WITNESS: Go ahead.
11
     BY MR. METZ:
12
           Q. Have you seen this document
13
     before?
14
           A. I don't think so. I should
     check again my documents cited.
15
16
                  (Document review.)
           A. I assume it would be under O
17
18
     for Ohio.
19
     BY MR. METZ:
20
           Q. I haven't checked. It could
21
     also be under 2010. I don't know.
22
           A. I don't think so.
23
           Q. Okay. You don't recognize it
     as you sit here?
24
           A. I don't.
25
```

- 1 Ο. Okay. I will represent to you 2. that Exhibit 31 is a final report and task 3 force recommendations from a body known as 4 the Ohio Prescription Drug Abuse Task Force. 5 Do you see that? 6 Α. Yes. 7 And in your inquiry and Q. 8 research into finding the key factors that 9 you try to be accounted for in your model, 10 did you at any point come to learn that Ohio 11 had commissioned a drug abuse task force 12 relating to the subject of prescription 13 drugs? 14 Α. I believe that I was aware that 15 there had been activity in Ohio related to 16 combatting the opioid epidemic. 17 Q. Okay. But you don't recall 18 seeing any report or other information about 19 that, do you? 20 I don't recall. Α. 21 Okay. Now, I want you to turn Ο.
- the section in which a later page appears.

Α.

22

23

24

25 Do you see that there's a Q.

Okay.

first to page 21, just so I can orient you to

- heading there that says How Did This Become
- ² an Epidemic?
- A. Yes, I do.
- 4 O. And there's some information
- 5 there followed by a chart, okay?
- 6 A. Yes.
- Q. If you turn to the next page,
- 8 the next -- the section at the top of page 22
- 9 talks about the law that we just considered,
- that we just looked at, and I'll just read it
- into the record.
- Under the heading Changes in
- 13 Clinical Pain Management, the document
- states: Growing recognition by professionals
- of the undertreatment of pain in the late
- 1990s prompted needed changes in clinical
- pain management guidelines at the national
- level, as well as changes in Ohio's law
- regarding the treatment of intractable pain.
- 20 As defined in Ohio law, intractable pain
- means a state of pain that is determined,
- 22 after reasonable medical efforts have been
- made to relieve the pain or cure its cause,
- to have a cause for which no treatment or
- cure is possible or for which none has been

```
1
     found.
2.
                   Do you see that?
3
            Α.
                   Yes.
4
            Q.
                   And you recall that's the
5
     definition we read from the statute a moment
6
     ago, correct?
7
                   It looks like it's verbatim.
            Α.
8
                   Okay. So the next paragraph
            Ο.
9
            To address the perception that
10
     prescribing adequate amounts of controlled
11
     substances would result in unnecessary
12
     scrutiny by regulatory authorities, Ohio's
13
     Intractable Pain Act provided that physicians
14
     treating intractable pain are not subject to
15
     disciplinary action when practicing in
16
     accordance with accepted and prevailing
17
     standards of care and rules adopted by the
18
     medical board delineating those standards.
19
                   Do you see that?
20
            Α.
                         And I quess now I see how
21
     the law connects to the state medical board
22
     standards.
                  They're clearly interlocking.
23
            Ο.
                   And then it says:
                                       Such
24
     fundamental changes in the recognition and
25
     treatment of pain contributed to increased
```

- prescribing and concomitant availability of
- and exposure to potent opioid analgesics,
- 3 pain medications.
- 4 Do you see that?
- 5 A. I do.
- Q. Okay. So prior to now, were
- you aware that an appointed task force
- 8 appointed by the government of the State of
- 9 Ohio had, in a report, concluded that the law
- we looked at a moment ago from 1997 had
- contributed to the levels of prescription
- opioids dispensed in Ohio during the period
- covered by your study?
- MR. SOBOL: Objection, form,
- asked and answered.
- 16 A. I wasn't aware of this specific
- report. Again, going back to the context of
- Dr. Perri's report and what I understand the
- allegations are in this matter, it does not
- come as a surprise to me that this was found.
- 21 And again, this explicitly references those
- state medical board guidelines.
- Those, as I understand it,
- plaintiffs intend to prove were a vehicle for
- increasing -- basically opening the flood

```
gates for opioid prescribing. So this simply
1
2.
     confirms that the State of Ohio has found
3
     that to be true.
4
     BY MR. METZ:
5
                   And you did not include in your
            Ο.
6
     model a variable intended to capture, for
7
     sales within Ohio, the influences of the
8
     statute, correct?
9
                   MR. SOBOL: Objection, asked
10
            and answered.
11
                   MR. METZ: It's really a
12
           yes-or-no question.
13
                   MR. SOBOL: Well, you can
14
            answer it however you think you need
15
            to.
16
                   I included in my model national
            Α.
17
     variables. And as I've noted, I believe
18
     factors such as these are why promotion was
19
     so effective in that early part of the period
20
     that I analyze.
21
                   In my view, it would not be
22
     appropriate to try to pull out this effect
23
     when it is all part of how promotion caused
24
     sales.
25
                   ///
```

- BY MR. METZ:

 2 Q. We
- Q. Well, in your view in -- as
- expressed in paragraph 73, it was necessary
- 4 as a robustness test to test the very
- 5 assumption you just stated to me as to
- 6 whether these events, events like this, had a
- 7 sufficiently strong influence to render
- 8 Model B inaccurate.
- 9 MR. SOBOL: Objection.
- 10 BY MR. METZ:
- 11 Q. Isn't that what you said in
- 12 your report?
- MR. SOBOL: Objection, asked
- and answered already.
- A. As I said in my report, I'm
- testing the form of the model. I do not -- I
- do not use Model C in calculating damages,
- but it is not my belief that those variables
- necessarily would occur in a but-for
- scenario.
- 21 And so Model C, the robustness
- check is around the specification, and while
- I understand that you respectfully disagree,
- I conclude that, in fact, Model C supports
- the use of Model B. But even if there were a

```
1
     significant dummy variable in Model C, it
2.
     wouldn't necessarily be the case that that
     variable would exist in the but-for world.
3
4
     BY MR. METZ:
5
                   Okay. So to -- if I could
            Ο.
6
     strip that down to a more relatable
7
     statement.
8
                   You're postulating a but-for
9
     world in which the State of Ohio's General
10
     Assembly does not enact the statute that we
11
     just looked at?
12
                   MR. SOBOL: Objection,
13
            mischaracterizes her testimony.
14
                   I don't know about the specific
            Α.
15
     law, but many of those events, including the
16
     state medical board guidelines, which appear
17
     to interact with the law, are posited by
18
     plaintiffs to have been caused by the conduct
19
     of defendants.
20
                   MR. METZ: Why don't we go off
21
            the record.
22
                   THE VIDEOGRAPHER: The time is
23
            3:26 p.m. We're now off the record.
24
                   (Recess taken, 3:26 p.m. to
25
            3:33 p.m.
```

```
1
                                       The time is
                   THE VIDEOGRAPHER:
2.
                       We're back on the record.
            3:33 p.m.
3
                       EXAMINATION
4
     BY MR. GEISE:
5
                   Professor Rosenthal, my name is
6
     Steve Geise.
                    I represent Walmart in this
7
            We had a chance to meet off the record
8
     and I just have a very few questions for you
9
     today because our time is running to a close.
10
                   In response to questions from
11
     Mr. Metz, you indicated you had not analyzed
12
     pharmacy conduct at all for purposes of your
13
     opinions; is that correct?
14
                   MR. SOBOL: Objection, asked
15
            and answered.
16
                   Yes, I do not analyze pharmacy
            Α.
17
     conduct in my analysis.
18
     BY MR. GEISE:
19
                   Yesterday in response to a
20
     question, you testified that distributors'
21
     conduct was outside the scope of your report.
22
     Is it true that retail pharmacy conduct is
23
     also outside the scope of your report?
24
                   MR. SOBOL: Objection.
25
                   My analysis does not include
            Α.
```

- 1 retail pharmacy conduct.
- 2 BY MR. GEISE:
- Q. The assignment that you were
- 4 given by plaintiffs' counsel did not include
- 5 considering any conduct by a retail pharmacy
- 6 defendant, correct?
- 7 A. My assignment pertains to the
- 8 marketing conduct and not to the conduct of
- ⁹ retail pharmacies.
- 10 Q. If you look at Exhibit 1 to
- your deposition, which is your expert report,
- in particular, your Figure 1 on page 19, this
- is your promotion ecosystem, correct?
- 14 A. Yes.
- Q. You would agree that retail
- pharmacy defendants are not part of that
- promotion ecosystem at all, correct?
- 18 A. Retail pharmacies are not part
- of the promotion ecosystem that I describe
- here.
- MR. GEISE: Thank you. Those
- are my questions.
- THE VIDEOGRAPHER: The time is
- 3:34 p.m. We're off the record.
- 25 (Recess taken, 3:34 p.m. to

```
1
            3:35 p.m.)
 2.
                   THE VIDEOGRAPHER: The time is
 3
            3:35 p.m. We're back on the record.
 4
                       EXAMINATION
 5
     BY MR. SOBOL:
 6
                   You were asked some questions
 7
     yesterday and today about the assignment that
 8
     you were given. The assignment you were
 9
     given was with respect to modeling the
10
     combined effect of certain manufacturer
11
     defendants' marketing, correct?
12
            Α.
                   Yes, that's correct.
13
                   The lawyers, though, didn't
            Ο.
14
     tell you what type of model you should use,
15
     correct?
16
            Α.
                   That's correct.
17
            Q.
                   You chose the aggregate model,
18
     correct?
19
            Α.
                   I chose the aggregate model to
20
     estimate aggregate impact, as I have
21
     described over the last day and a half,
22
     because the aggregate model allows me to
23
     capture spillover effects and is the most
24
     efficient way to estimate the combined effect
25
     of defendants' alleged marketing misconduct.
```

```
1
                    MR. SOBOL: Nothing further.
 2
                    MR. ROTH: No follow-up here.
 3
                    THE VIDEOGRAPHER:
                                         That
            concludes the deposition of Meredith
 4
            Rosenthal. The time is 3:36 p.m., and
 5
            we're now off the record.
6
 7
                    (Proceedings recessed at
 8
            3:36 p.m.)
 9
                          --000--
10
11
12
13
14
15
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21
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23
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```

```
1
                       CERTIFICATE
2.
                 I, MICHAEL E. MILLER, Fellow of
     the Academy of Professional Reporters,
     Registered Diplomate Reporter, Certified
3
     Realtime Reporter, Certified Court Reporter
     and Notary Public, do hereby certify that
4
     prior to the commencement of the examination,
     MEREDITH B. ROSENTHAL, Ph.D. was duly sworn
5
     by me to testify to the truth, the whole
     truth and nothing but the truth.
6
7
                 I DO FURTHER CERTIFY that the
     foregoing is a verbatim transcript of the
     testimony as taken stenographically by and
8
     before me at the time, place and on the date
     hereinbefore set forth, to the best of my
9
     ability.
10
                 I DO FURTHER CERTIFY that pursuant
     to FRCP Rule 30, signature of the witness was
11
     not requested by the witness or other party
     before the conclusion of the deposition.
12
                 I DO FURTHER CERTIFY that I am
13
     neither a relative nor employee nor attorney
     nor counsel of any of the parties to this
14
     action, and that I am neither a relative nor
     employee of such attorney or counsel, and
15
     that I am not financially interested in the
16
     action.
17
18
     MICHAEL E. MILLER, FAPR, RDR, CRR
     Fellow of the Academy of Professional Reporters
19
     NCRA Registered Diplomate Reporter
20
     NCRA Certified Realtime Reporter
     Certified Court Reporter
21
     Notary Public
     My Commission Expires: 7/9/2020
22
     Dated: May 6, 2019
23
24
25
```

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1
                 INSTRUCTIONS TO WITNESS
 2.
 3
                 Please read your deposition over
 4
     carefully and make any necessary corrections.
 5
     You should state the reason in the
 6
     appropriate space on the errata sheet for any
 7
     corrections that are made.
                 After doing so, please sign the
 8
 9
     errata sheet and date it.
                 You are signing same subject to
10
11
     the changes you have noted on the errata
12
     sheet, which will be attached to your
13
     deposition.
14
                 It is imperative that you return
15
     the original errata sheet to the deposing
16
     attorney within thirty (30) days of receipt
     of the deposition transcript by you. If you
17
18
     fail to do so, the deposition transcript may
19
     be deemed to be accurate and may be used in
20
     court.
21
22
23
24
25
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1		ERRATA
2	PAGE	LINE CHANGE
3		
4		REASON:
5		
6		REASON:
7		
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20		REASON:
21		
22		REASON:
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24		REASON:
25		

1	ACKNOWLEDGMENT OF DEPONENT				
2					
3					
4	I, MEREDITH B. ROSENTHAL, Ph.D.,				
	do hereby certify that I have read the				
5	foregoing pages and that the same is a				
	correct transcription of the answers given by				
6	me to the questions therein propounded,				
	except for the corrections or changes in form				
7	or substance, if any, noted in the attached				
	Errata Sheet.				
8					
9					
10					
11					
12					
	MEREDITH B. ROSENTHAL, Ph.D. DATE				
13					
14					
15	Subscribed and sworn to before me this				
16	day of, 20				
17	My commission expires:				
18 19					
20	Not one Dublin				
21	Notary Public				
22					
23					
24					
25					
-					

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1			LAWYER'S NOTES
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3	PAGE	LINE	
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